IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TEXAS

UNITED STATES OF AMERICA ex rel. Esther Sullivan, Relator,	§	
	§	Civil Action No. 5:13-cv-0244-OLG
STATE OF ARKANSAS ex rel. Esther Sullivan, Relator,	§	
	§	JURY TRIAL DEMANDED
STATE OF CALIFORNIA ex rel. Esther Sullivan, Relator,	§	
STATE OF COLORADO ex rel. Esther Sullivan, Relator,	§	
STATE OF CONNECTICUT ex rel. Esther Sullivan, Relator,	§	
STATE OF DELAWARE ex rel. Esther Sullivan, Relator,	§	
DISTRICT OF COLUMBIA ex rel. Esther Sullivan, Relator,	§	
STATE OF FLORIDA ex rel. Esther Sullivan, Relator,	§	
STATE OF GEORGIA ex rel. Esther Sullivan, Relator,	§	
STATE OF HAWAII ex rel. Esther Sullivan, Relator,	§	
STATE OF ILLINOIS ex rel. Esther Sullivan, Relator,	§	
STATE OF INDIANA ex rel. Esther Sullivan, Relator,	§	
STATE OF IOWA ex rel. Esther Sullivan, Relator,	§	
STATE OF LOUISIANA ex rel. Esther Sullivan, Relator,	§	
STATE OF MASSACHUSETTS ex rel.	§	

Esther Sullivan, Relator,	§
	§
STATE OF MICHIGAN ex rel. Esther Sullivan, Relator,	§
	§
	§
STATE OF MONTANA ex rel. Esther Sullivan, Relator,	§
	§
	§
STATE OF NEVADA ex rel. Esther Sullivan, Relator,	§
	§
	§
STATE OF NEW HAMPSHIRE ex rel. Esther Sullivan, Relator,	§
	§
	§
STATE OF NEW JERSEY ex rel. Esther Sullivan, Relator,	§
	§
	§
STATE OF NEW YORK ex rel. Esther Sullivan, Relator,	§
	§
	§
STATE OF NORTH CAROLINA ex rel. Esther Sullivan, Relator,	§
	§
	§
STATE OF OKLAHOMA ex rel. Esther Sullivan, Relator,	§
	§
	§
STATE OF RHODE ISLAND ex rel. Esther Sullivan, Relator,	§
	§
	§
STATE OF TENNESSEE ex rel. Esther Sullivan, Relator,	§
	§
	§
STATE OF TEXAS ex rel. Esther Sullivan, Relator,	§
	§
	§
STATE OF VIRGINIA ex rel. Esther Sullivan, Relator,	§
	§
	§
STATE OF WISCONSIN ex rel. Esther Sullivan, Relator,	§
	§
	§
vs.	§
	§
ATRIUM MEDICAL CORPORATION, Defendant.	§

SECOND AMENDED COMPLAINT FOR DAMAGES UNDER THE FEDERAL FALSE CLAIMS ACT AND VARIOUS STATE FALSE CLAIMS ACTS AND DEMAND FOR JURY TRIAL

I. INTRODUCTION

1. In the instant lawsuit, relator Esther Sullivan alleges that Atrium Medical Corporation ("Atrium") violated the False Claims Act, 31 U.S.C. § 3729 *et seq.*, by engaging in a widespread, nationwide scheme to promote its iCAST stent, a Class II device cleared through the 510K process, for unapproved uses. The stent is only cleared for use in the "the treatment of tracheobronchial strictures produced by malignant neoplasms," per Atrium's intended use, as it stated to the FDA in its 510K application. But Atrium never intended the iCAST stent to be used this way. At the time it sought clearance by the FDA, Atrium intended the iCAST to be used for other purposes entirely, including for placement in the renal and iliac arteries, in addition to use in the aorta, and the carotid, pulmonary, splenic, subclavian, mesenteric, and femoral arteries. As Atrium planned, after the FDA granted the 510K clearance, Atrium exclusively promoted the iCAST for these unapproved uses, and not for the treatment of tracheobronchial strictures. The use of the iCAST stent under these circumstances was not medically necessary because it was experimental, investigational, unapproved, and in fact, on various occasions, when used in these unapproved ways, the stent failed. Atrium's placement of the iCAST stent into the stream of commerce also constituted misbranding in violation of 21 U.S.C. § 352(f), because Atrium never intended for the iCAST stent to be used for its cleared indication. Since the instructions that accompanied the iCAST, which were cleared by the FDA, were only for use of the device in tracheobronchial procedures, the iCAST was misbranded because it failed to bear adequate

instruction for the unapproved uses that Atrium knew and intended it be used for. This misbranding also rendered the product substandard. As already stated, on many occasions it failed when it was used for unapproved indications.

2. In furtherance of its long term marketing plans, in order to encourage physicians and hospitals, including VA hospitals, to purchase iCAST stents and use them for unapproved uses, Atrium Medical Corporation provided free stents, grants, and kickbacks in various forms, all of which violated the Anti-Kickback Statute ("AKS"), 42 U.S.C. § 1320a-7b(b). Defendant therefore knowingly made and induced fraudulent statements and claims material to the federal and state Governments' decisions to pay monies for hundreds of thousands of reimbursement claims by healthcare providers for unapproved, noncovered medical devices for over six years.

3. Plaintiff-Relator Sullivan estimates that in 2007, Atrium did approximately $40 million in sales of the iCAST stent. In 2008, Atrium sold $46 million of the stents; in 2009, $54 million; in 2010, $62 million; in 2011, $80 million; and in 2012, $100 million. In 2011, Atrium's revenues in the United States associated with the iCAST were about $57,000,000. On information, Ms. Sullivan believes close to 100% of these stents were used for unapproved purposes. Furthermore, she believes, on information, that over 90% of the iCAST stents were ultimately paid for by Medicare, military hospitals, the VA, and Medicaid as the vast majority of individuals with vascular blockages are over the age of 65.

II. PARTIES

4. Relator **Esther Sullivan** is a citizen of the Unites States and resides in Raleigh, North Carolina. Ms. Sullivan was employed by Atrium as a territory business manager for the Raleigh, North Carolina territory between 2007 and 2012. During that period of time, Ms.

Sullivan sold Atrium's vascular grafts, drug delivery catheters, and balloon expandable covered stents called iCAST. Ninety-five percent of Ms. Sullivan's sales were for iCAST stents.

5. The facts averred herein are based upon the direct, personal observations of Ms. Sullivan and documents in her possession. Ms. Sullivan is not aware of any public disclosure of the facts or information contained in this complaint.

6. Ms. Sullivan provided to the United States Attorney and the Attorneys General of all of the States named in the caption and the District of Columbia a full disclosure of substantially all material facts, as required by the False Claims Act, 31 U.S.C. § 3730(b)(2), and relevant state statutes, prior to filing the instant complaint.

7. Defendant **Atrium Medical Corporation** is a private company that manufactures medical devices. The company was founded in 1981 and is headquartered at 5 Wentworth Drive, Hudson, New Hampshire, 03051. It is incorporated in the state of Delaware. In about October 2011, GETINGE GROUP of Sweden and its subsidiary, MAQUET Cardiovascular, acquired Atrium for $680 million. Atrium functions as an independent business unit of MAQUET.

III. JURISDICTION AND VENUE

9. This action arises under the False Claims Act, 31 U.S.C. §§ 3729 *et seq.* This Court has jurisdiction over this case pursuant to 31 U.S.C. §§ 3732(a) and 3730(b). This court also has jurisdiction pursuant to 28 U.S.C. § 1345 and 28 U.S.C. § 1331. Supplemental jurisdiction for Counts 5 - 33 arises under 28 U.S.C. § 1367, since these claims are so related to the federal claims that they form part of the same case or controversy under Article III of the U.S. Constitution.

10. At all times material to this Complaint Atrium Medical Corporation regularly conducted substantial business within the State of Texas, maintained permanent employees and offices in Texas, and made and is making significant sales within Texas. Defendants are thus subject to personal jurisdiction in Texas.

11. Venue is proper in this district pursuant to 31 U.S.C. § 3732(a) because Atrium Medical Corporation transacts business in this district.

IV. FACTS

A. THE iCAST STENT

12. The iCAST covered stent is a Class II medical device. It is a balloon-expandable covered stent. The FDA cleared its use pursuant to the 510K process in September 2004. The FDA cleared the iCAST covered stent for "the treatment of tracheobronchial strictures produced by malignant neoplasms." The iCAST has not been approved for any other use, and Defendant admits that its iCAST stent has not been established as safe and effective – that is, FDA approved – for vascular use. *See* Defendant Atrium Medical Corporation's Objections and Response to Relator's First Set of Interrogatories at 7, attached as Exhibit 1. Further, the current label for the iCAST stent specifically states, "The safety and effectiveness of this device for use in the vascular system have not been established and can result in serious harm and/or death." *Id.*

13. The stents come in several sizes, and range in price from about $2300 to $2800.

14. When Atrium sought to have the iCAST stent cleared for use as a Class II medical device, it never intended to actually market or promote it for use for tracheobronchial strictures. Individuals at Atrium, including the inventors of the iCAST, Ted Karwoski and Paul Martakos, told Ms. Sullivan that the product was never designed for tracheobronchial strictures. In fact, the company initially intended the product to be used for cardiac procedures. However, in order to

avoid the expensive and time-consuming Class III PMA procedure that the company would have to engage in to have the iCAST approved for use in cardiac procedures or the renal or iliac arteries, Atrium decided to falsely represent to the FDA that the device was similar to other devices used to treat tracheobronchial strictures and that it was intended to be used that way. In fact, Ms. Sullivan was told that Atrium got clearance "for anything we could" just so that it could put iCAST on the market.

15. Patents and trademarks for the iCAST also make clear that Atrium's intended purpose for the stent was for use in the vascular system. For example, U.S. Patent No. 6,010,529 (Jan. 2000), which include as inventors Mr. Karwoski and Mr. Martakos, is for an "expandable shielded vessel support" that is covered by PTFE material. The description states that "the present invention relates to vessels and vascular support structures, such as stays, stents and support rings which are used for maintaining open a biological passage, such as an artery." A similar patent that lists Messrs. Karwoski and Martakos, U.S. Patent No. 6,270,523 B1, says the same thing, and also lists as supporting materials/other publications an article on "Stented Grafts for the Treatment of Arterial Vascular Disease." Earlier patents for the same device describe it as a "vascular endoprosthesis." A June 2004 trademark application for the iCAST describes the product as "medical devices, namely stents and stent deployment instruments, stent deployment catheters, all for tracheal, vascular, neuro, gastro-intestinal or urological interventional surgeries."

B. PROMOTION OF THE iCAST STENT FOR UNAPPROVED USES

16. During Ms. Sullivan's tenure as a sales representative at Atrium, Atrium almost exclusively marketed the iCAST stent to physicians and hospitals for unapproved uses. Ms. Sullivan herself was never trained or instructed to market the iCAST for use to treat

tracheobronchial strictures, she never sold a stent for that purpose, and she never attended or was made aware of any procedure in which the iCAST stent was used to treat tracheobronchial strictures. In fact, Ms. Sullivan believes, on information, that the iCAST stent would rarely, if ever, be placed in the trachea because, as she was taught in her company trainings, as a covered stent, it crushes easily, and thus would pose a risk in the trachea, a physical location where it could easily be crushed. In fact, during a training session in 2007, Ms. Sullivan heard Mike Dupont, who was then a trainer for Atrium and is currently the President of Marketing, tell sales reps, "You will never see a doctor place one of these stents in the trach."

17. Instead of promoting the iCAST for the use for which it was cleared, during the entire time Ms. Sullivan was employed at Atrium, she and the other sales representatives were trained and instructed by management to market the iCAST stent solely for unapproved uses in the iliac, renal, and carotid arteries, as well as other unapproved uses, despite the fact that the iCAST has never been approved by the FDA for these uses. Indeed, a training binder Atrium provided to sales reps in about 2011 entitled the "Covered Stent Clinical Experience" that contained 69 reprints of papers and articles involving uses of the iCAST stent (known in Europe as the V12 or Advanta stent) appears to have only one reprint that involves placement of the stent in the trachea. All the other reprints involve unapproved, and often unusual ways, to use the iCAST stent, including in the aorta, iliac, renal, carotid, pulmonary, splenic, subclavian, mesenteric, and femoral arteries.

18. In addition, a "Selling Strategies" guide provided to sales reps in 2007 explains to those reps that Atrium's "goal" was to "Expand Horizon on How to Sell iCAST/Advanta 12." That guide also makes clear that Atrium placed advertisements for the iCAST in *Endovascular*

Today, clearly in an effort to appeal to surgeons doing endovascular stenting, not to surgeons who would do tracheobronchial stenting.[1]

19. When Ms. Sullivan asked Brian Suddarth, National Sales Manager, at a 2011 National Sales Meeting in Florida whether he was concerned that the company was solely promoting the iCAST for off-label – that is, unapproved – uses, he told her, "If we get dinged by the FDA, we'll write the check. It's a price of doing business, and we'll move on." Nevertheless, Atrium clearly was concerned that they would eventually get "dinged" for their promotion for unapproved uses. In about 2010, Atrium provided sales reps with "Off Label Product Use Information Request" cards that were provided to physicians for their signatures. The cards make it seem as if any information about unapproved uses provided by the physicians was requested by them, but sales reps were instructed to, and did, provide these cards to all the physicians they called upon and had them sign them as a matter of course, so that they would then have "free reign" to promote unapproved uses to them as instructed by Atrium, Ms. Sullivan was told. Around the same time, Atrium requested that all sales reps place an automatic message at the bottom of their e-mails stating that the iCAST stent was only "approved"[2] for tracheobronchial use. Atrium did not place this statement on their employees' e-mails themselves, and despite the request, Ms. Sullivan believes, based on her observation of hundreds of emails, that few, if any, employees placed this disclaimer at the bottom of their e-mails.

---

[1] *Endovascular Today's* website states it is "a publication dedicated to bringing . . . comprehensive coverage of all the latest technology, techniques, and developments in the endovascular field. Our Editorial Advisory Board is composed of the top endovascular specialists, including interventional cardiologists, interventional radiologists, vascular surgeons, neurologists, and vascular medicine practitioners, and our publication is read by an audience of more than 22,000 members of the endovascular community." http://bmctoday.net/evtoday/ (last viewed Mar. 7, 2013).

[2] The iCAST was not, in fact, ever "approved" by the FDA. Instead, it was "cleared" under the 510(k) process.

1. Promotion for Unapproved Use in the Carotid Artery

20. When Ms. Sullivan first began at Atrium, she received training from managers and others at Atrium on how to promote the iCAST for unapproved uses. She was involved in role plays, discussions of clinical trials, and talks about company "best practices." All of this training involved the unapproved use of the iCAST stent and how discussions about unapproved uses with doctors should be handled. As stated already, Ms. Sullivan did not receive any training involving the FDA-cleared use of iCAST stents to treat tracheobronchial strictures.

21. Initially, when Ms. Sullivan began at Atrium in 2007, she was trained to promote the iCAST stent for use in the carotid artery. She recalls that Mike Dupont and Chad Carlton, who is now the Executive Vice-President of Global Marketing, discussed carotid artery stenting. At this training, Ms. Sullivan was given a document called "Answers to Questions Posed at Advanced Training April 2005." The training provided sales reps with responses to typical questions asked by physicians. In response to the question, "Can it be used in the Carotid Arteries?" Sales reps are trained to say that "the product has been used in the Carotids." The document does state that in the U.S., this is an off-label (that is, unapproved) use "and cannot be recommended by Atrium." However, the sales reps are also told and the materials specifically state that they should let doctors know that "[i]t is totally at the physicians [*sic*] discretion as to where a stent may be placed." The sheet also lets reps know that it is "vitally important that [physicians] understand the limitations of a balloon expandable stent, specifically superficial placement that may be prone to crushing forces, and relative stiffness of the stent."

22. When Ms. Sullivan was provided training on this sheet, she recalls that Chad Carlton said that the iCAST stent works fine in the carotid arteries, but that physicians should be aware that it ought not be placed in the external portion of the carotid or too high, in the internal

carotid, as in either of those places it could get crushed and cut off the blood flow to the brain. Indeed, the document itself makes clear, "if a doctor wants to use the stent for carotid we say no (crushable) yet if he means carotid where the lesion is under the skull then our stent would be protected – reps need to [k[now how to ask the doctor further questions beyond 'carotid sorry we can't do it." Thus, despite knowing of the dangers inherent in using the iCAST stent in the carotid, Atrium continued to encourage its sales reps to promote it for this unapproved use.

23. Indeed, at the same training in 2007, Ms. Sullivan was given a document entitled "Selling Strategies" by Mike Dupont. Eight or nine sales people who also attended the training also received the document, including Dee Johnson, Lee Layman, and Dan Brenner. Mike Dupont and Chad Carlton spent several hours teaching the sales reps how to promote the iCAST using this document, which essentially provided scenarios to guide and train the sales people in providing proper messaging in different circumstances. One of these scenarios was entitled "Covered Stent Role Play #8—Can I Use this in the Carotid?" The scenario and objectives of the sales rep are described as follows:

> Dr. Crouton is a big wig at Sakajoweah hospital, he has a Carotid case coming up and for some reason the iCAST came to mind. You briefly showed him the product last week but didn't get much time with him. For some reason you are the lucky one and go the call.
>
> Objectives:
> Clearly identify the strengths and weaknesses of the Atrium covered stent and direct Dr. Crouton as to whether he should use this product for his Carotid case.

24. As described above, Atrium also provided sales reps with a training binder entitled the "Covered Stent Clinical Experience" that contained reprints of papers and articles

involving uses of the iCAST stent (known in Europe as the V12 or Advanta stent). Nine of these reprints are about stenting the carotid artery and use of the iCAST stent to do so.

25. In addition to arming sales reps with reprints that educated the sales reps on unapproved uses of the iCAST and providing them with "ammunition" to give to doctors to support these uses, in the form of angiograms of actual unapproved uses of the iCAST in real patients, false billing code cards and the reprints of studies noted above, Atrium training also involved the discussion of "best practices" used to persuade doctors to use the iCAST for unapproved indications. During "best practices" training, successful sales reps would share with new trainees and other sales reps their methods for promotion. For example, at an Atrium National Sales at the J.W. Marriott in Orlando, FL in about 2010, Pat Racanelli, a sales manager, presented a new "best practice" that all sales reps were supposed to implement that required the sales reps to ask physicians to provide them with angiograms from their patients. Sales reps were instructed to tell physicians that they were learning to read angiograms and ask them to share recent angiograms with them. If the angiograms were for patients with conditions that the Company believed could be treated with an iCAST stent, such as blockage of the carotid artery, iliac artery stenosis or occlusion, or would involve stenting the renal arteries, sales reps were instructed to then ask the physician if they could be present in the operating room during the surgery. Atrium trained its sales reps to bring iCAST stents into the operating room, and to suggest their use to physicians during surgery.

26. Ms. Sullivan and her fellow Atrium sales reps—approximately eighty of them in eight separate regions across the U.S.—actually used this method with physicians, reviewed angiograms and obtained invitations to operating rooms, where they suggested and provided

iCAST stents for use in procedures involving the carotid artery, the iliac artery, renal arteries as well as for other unapproved uses (e.g. mesenteric).

27. Atrium was aware that placement of an iCAST stent in the carotid artery was dangerous because the stent could easily be crushed by head and jaw movement. In fact, Ms. Sullivan refused to market the iCAST stent in this manner to her surgeons because one of them, Dr. Jeffrey Lawson of Duke University, explained to Ms. Sullivan that because iCAST is flexible, if it is placed in the wrong location in the carotid, it can be crushed and the blood supply to the brain cut off. Because of these dangers, stenting of the carotid artery fell out of favor in about 2010 and Medicare stopped paying for this procedure around the same time. For these reasons, Atrium stopped promoting it for this use. But Atrium continues to promote the iCAST for use in the iliac artery, renal arteries, and in other locations.

2. Promotion for Unapproved Use in the Iliac Artery

28. In addition to encouraging its sales reps to promote the iCAST for use in the carotid artery, Atrium trained Ms. Sullivan and its other sales reps to promote the iCAST for use to improve blood flow and improve luminal diameter in the iliac artery, despite a lack of approval for these uses.

29. From the time Ms. Sullivan began her career at Atrium through the time she left, the Company trained sales reps to promote the iCAST by using role playing The "Sales Strategies" document described above also included a role play entitled "Why Would I Use A Covered Stent in the Iliac?" The scenario and objectives of the sales rep are described as follows:

> Overview:
> Dr. Palmetto has about five minutes before his next case and the lab technician has arranged for you to see her. You have learned from the lab

> technician Jake that Dr. Palmetto has a few covered stents on the shelf but only uses them on occasion for trauma or occasional dissection.
>
> Objectives:
> Discuss the product and why ours should be on the shelf. Talk to Dr. Palmetto about using the product for more than just trauma or dissections.

30. This scenario was used to train Ms. Sullivan and the other sales reps to discuss the use of the iCAST stent in the iliac artery. Another scenario set forth in the same document was for the same purpose. In a section called "Covered Stent Role Play #6—Why Would I Use A Balloon Expandable Product," Atrium provided the following scenario and objectives for training the sales reps:

> Overview:
> Dr. BEX [*sic*] has agreed to see you and learn about the iCAST. Dr. Bex, [*sic*] uses covered stents but presently uses the Viabahn and likes the self-expanding stent product. He occasionally uses the product on complex lesions in the Iliac.
>
> Objectives:
> Help explain to Dr. Bex why a Balloon Expandable Covered Stent would be better than a self-expanding stent in the Iliac and in particular why the Atrium Covered Stent would be better.

31. As this training scenario shows, Atrium specifically trained its sales reps to promote the iCAST stent as a competitor to Gore's Viabahn stent. The Viabahn is a covered self-expanding stent. Because the FDA considers stents used in the vascular system to be high-risk devices subject to strict regulation, the Viabahn stent is a Class III medical device and thus was approved through the PMA process. *See United States ex rel. Nowak v. Medtronic, Inc.*, 806 F. Supp. 2d 310, 320 (D. Mass. 2011) ("In contrast to biliary stents, the FDA considers stents used in the vascular system to be high-risk devices subject to regulation as Class III devices.") The

FDA approved the Viabahn stent for use to improve blood flow in the femoral arteries and to improve blood flow in patients with symptomatic peripheral arterial disease in iliac artery lesions. Unlike the iCAST stent, then, the Viabahn stent has been approved as being safe and effective for use in the iliac artery. Nevertheless, Atrium instructed its sales reps specifically to falsely represent that the iCAST stent was "better" than the Viabahn for use in the iliac.

32. Indeed, a promotional piece that Atrium provided to Ms. Sullivan and its other sales reps entitled "Competitive Comparison" specifically illustrates for the physicians the advantages of using the iCAST instead of the Viabahn. The document states that the "Atrium iCAST covered stent is approved [*sic*] in the USA for Tracheobronchial use only. This product has not been approved [*sic*] in the vascular system and as such it is the policy of Atrium Medical Corporation not to promote off-labeluse of its products." Despite this disclaimer, Atrium instructed sales reps to use the comparison information within the document to illustrate to physicians why the iCAST was "better" than the Viabahn for use in the iliac artery.

33. In addition to selling the iCAST stent as a competitor to the Viabahn stent, Atrium sales reps also sold the iCAST as a competitor to Cordis Corporation's SMART stent, also a Class III device approved through the PMA process. The SMART stent is a bare metal stent approved by the FDA to improve luminal diameter in patients with symptomatic atherosclerotic disease of the common and/or external iliac artery. In comparison to the iCAST stent, which sells for between $2300 and $2800, bare metal stents such as the SMART sell for about $400.

34. As described above, Atrium trained Ms. Sullivan and other Atrium sales reps to ask physicians to allow them to review angiograms and to attend surgeries in the operating room. Atrium reps would specifically ask to attend surgeries involving conditions that would likely

lead to stenting of the iliac artery so that they would be able to recommend use of the iCAST stent during the procedure.

35. Starting in about 2009, Atrium also armed its sales people with "representative" angiograms and CT scans of "cases" that could be loaded from the company server onto the sales reps' iPod Touch devices and later on their iPads. In each case, an iCAST stent had been used to treat the patient. Many of these cases involved the use of the iCAST stent in the iliac artery. Atrium sales reps used these cases to discuss unapproved uses of the iCAST stents with physicians. Atrium removed these cases from its central server in about 2011 and told sales reps that they could no longer be used due to FDA restrictions on promotion for unapproved uses.

36. Atrium also provided its sales reps with information about clinical papers that purported to support the use of iCAST stents. As part of training, Atrium provided its sales reps with a small brochure entitled "Covered Stent Clinical Paper Summaries." The brochure provided bullet point summaries for six papers, none of which involved the use of the iCAST stent for tracheobronchial use. Instead, the papers involve the use of stents, including the iCAST, to "treat aorto-iliac lesions" and "to treat iliac occlusive disease." One paper also looked retrospectively at the patency rate of the iCAST when placed in the iliac.

37. As described above, Atrium also provided sales reps with the "Covered Stent Clinical Experience" training binder. That binder contained thirty-six reprints under the heading "Aortoiliac."

38. Throughout Ms. Sullivan's time as a territory business manager at Atrium, the company kept promising its sales representatives that it was going to get PMA approval from the FDA. The running joke at the company was that every year it was expecting to get this approval "in the fourth quarter." Even Jeff Harris, the Vice President of Sales for North America, used to

joke about this. As early as 2007, when Ms. Sullivan began her career at the Company, she was given training that indicated that the company was "working on plans to obtain a vascular FDA approval for the V12." The Company trained reps to tell physicians who asked why Atrium had not received FDA approval to use the iCAST in the vascular system the following: "Vascular approval requires an IDE and PMA study to obtain approval of a vascular indication. To date very few stent products have been approved for such usage even after completing these studies. The IDE/PMA studies will take a couple of years to complete and require several millions of dollars. However, it is our intent to obtain approval for the Advanta V12 for vascular usage." Nevertheless, it still has not obtained FDA approval for the iCAST stent to be used outside its cleared indication. *See* Exhibit 1 at 7.

39. Despite the lack of approval from the FDA, Atrium promoted the iCAST stent for use in the iliac artery, and Atrium's promotion led to physicians using it for this procedure. Ms. Sullivan recalls that during her tenure at Atrium, she marketed the stent to and was in the operating room with Dr. Robert Albrecht and Dr. Clinton Atkinson of First Health Moore Regional Hospital in Pinehurst, NC, for several cases in which each of them implanted the iCAST in the iliac artery. She also recalls being present for several procedures in which Dr. Jonathan Berry the Chief of the Cardiovascular Section at Moses Cone Hospital and Medical Director of the Moses Cone Peripheral Vascular Lab used the iCAST for iliac stenting. Ms. Sullivan was also present for several procedures in which Dr. Mike Cooper of Moses Cone used the iCAST for iliac stenting. Ms. Sullivan was also present in the operating room at the Durham VA Medical Center on many separate occasions when Dr. Mike Miller, Dr. Richard McCann, and Dr. Leila Murebee each used the iCAST stent in the iliac. She also recalls being present

when Dr. Ravish Sachar of Wake Heart & Vascular in Raleigh, NC, did iliac stenting with the iCAST. Each of these uses was unapproved.

3. Promotion for Unapproved Use in the Renal Arteries

40. Atrium also promoted the iCAST stent for unapproved use in the renal arteries. In the role playing training document entitled "Selling Strategies" described above, the Company provided a scenario for training the sales people entitled, "Why Would I Use A Covered Stent in the Renal?" The "overview" provided described a "Dr. Aspen" who "has just agreed to see you. You hear that he does more renal interventions than anyone in the area. Deb the technician has told him about the fact that the product is balloon expandable and 7Fr, which has intrigued him." The document states that the objectives under these circumstances for the sales rep are: "discuss possible benefits or uses of Renal Sized covered stent (i.e. dissections, aneurysms, restenosis, occlusive disease and emboli). Mention key features of use to him like flaring or post dilation."

41. The "Covered Stent Clinical Paper Summaries" and the "Covered Stent Clinical Experience" binder provided to sales reps included descriptions of papers and reprints about stenting the renal arteries.

42. In addition, many of the "cases" that Atrium provided to its employees to download from its server to show physicians that illustrated different uses of the iCAST stent involved placement of the stents in the renal arteries.

43. Atrium also trained its sales reps to promote the iCAST for the unapproved use in the renal arteries by referring to well-known "opinion leaders" who were using it this way. For example, Ms. Sullivan was told to tell physicians that Dr. Rajesh Dave, a well-known interventional cardiologist who used to be at Pinnacle Health in Harrisburg, PA and who is now at Holy Spirit Cardiovascular Institute there, was using the device in both the renal and iliac

arteries with success. Some of Dr. Dave's successful cases were included in the cases that Atrium provided to sales reps for download, and the reps were trained to then show these cases to physicians. Duke University, which is in Ms. Sullivan's territory, did a trial on renal stents that shows that smaller stents have less occlusion. Atrium instructed its sales people to reference this trial and tell physicians that Duke was using the smaller iCAST stents for this purpose. Ms. Sullivan knows that this is an utter misrepresentation. Because she has Duke in her territory, she knows that the physicians at Duke never used iCAST stents in the renal arteries. Nevertheless, Atrium continued to promote the iCAST using this misrepresentation.

44. Atrium's promotion of the iCAST for the unapproved use in the renal arteries actually led to physicians using the device in this manner. For example, Ms. Sullivan was present at a few cases in the operating room with Dr. Robert Albrecht of First Health Moore Regional in Pinehurst, NC, when he implanted the iCAST in a patient's renal arteries. She also recalls Dr. Mike Cooper of Moses Cone in Greensboro, NC, doing a few renal implants with the iCAST. Ms. Sullivan also attended procedures at the Durham VA Medical Center in which Dr. Richard McCann and Dr. Mike Miller used the iCAST for renal stenting. Dr. David Weatherford of New Hanover Regional Medical Center in Wilmington, NC, also did many renal cases using the iCAST stent.

45. Ms. Sullivan believes that using the iCAST in the renal arteries did not have a medically sound basis. First, as was told to her by one physician, renal stenting has not been proven to lower creatinine levels or hypertension, as the Atrium sales reps had been instructed to say.[3] Second, it is difficult to place stents in the renal arteries because of anatomy, as Ms.

[3] Creatinine is a breakdown product of creatine phosphate in muscle. Serum creatinine is an important indicator of renal health that is excreted unchanged by the kidneys. Blood creatinine levels may be used alone to calculate the

Sullivan has been told by her physician clients including Dr. Kimberley Hansen. For these reasons and others, renal stenting is rarely safe and effective.

4. Other Promotion for Unapproved Uses

46. As set forth above, Atrium armed its sales representatives to have reprints of articles for all sorts of uses of the iCAST, including unapproved uses in the aorta, iliac, renal, carotid, pulmonary, splenic, subclavian, mesenteric, and femoral arteries.

47. In addition, in its role playing training document, Atrium guided its sales reps in how to answer the question, "Can I use this in an A_V Access Patient." The document sets the following scenario: "Dr. Idio currently uses the Fluency for his A-V Access Grafts. He has seen the iCAST before and wants to use it shortly. He has asked your advice about whether he could use this on a particular case A-V Access Case [*sic*]." It outlines the objectives for the sales rep as "[c]learly identify[ing] the strengths and weaknesses of the Atrium covered stent and direct Dr. Idio as to whether he should use this product for his next A-V Access Case."

48. Ms. Sullivan also recalls receiving training from Atrium at its National Sales Meeting in February 2011 at the Shingle Creek Resort in Orlando, FL on "new practices" that involved using the iCAST stent as an endoconduit for a stent graft for the aorta for aneurism cases. Atrium was particularly interested in this specific unapproved use, because it required the placement of several iCAST stents, meaning that Atrium would profit more from such procedures.

---

estimated glomerular filatration rate (GFR) a measurement of renal function. Serum creatinine is commonly used, therefore, as an indicator of renal function.

C. MISREPRESENTATIONS TO GOVERNMENT-EMPLOYED PHYSICIANS

49. In promoting the iCAST stent for the unapproved use in the carotid, iliac, and renal arteries, among other uses, as set forth above, Atrium and its sales force made material misrepresentations about the safety and efficacy of these devices to physicians, including physicians at VA and Army hospitals. Indeed one of Ms. Sullivan's accounts was the Veterans Administration Hospital in Durham, North Carolina. Pursuant to her training from Atrium, Ms. Sullivan marketed the iCAST stents there and was also present in the operating room or office for over 15 procedures in which she provided advice to the surgeons about the unapproved use of iCAST stents. All of these procedures took place between 2007-2011 and involved the use of iCAST stents in the iliac artery, the renal arteries, the mesenteric arteries or the subclavian arteries. None of these procedures involved an approved use of the iCAST stent. In all of these cases, the implantation of the iCAST stents occurred due to marketing for unapproved uses that Atrium provided to the physicians at the VA and due to Ms. Sullivan's recommendations to VA surgeons to use the iCAST in procedures for which it was not approved. The Government paid for all of these surgeries and for the physician services associated with these surgeries.

50. In addition to the training Atrium provided to its sales reps about how to promote the iCAST for unapproved uses, Atrium also trained its sales people to make other types of misrepresentations to physicians, including VA and Army physicians, in order to justify the use of the iCAST device.

51. Specifically, the iCAST device is much more expensive than bare metal stents. While the iCAST device can sell for between $2300 and $2800, bare metal stents, such as Cordis' SMART stent, sell for about $400. In order to justify to physicians the price of the iCAST device, Atrium instructed its sales force to tell physicians that bare metal stents were only

a "short-term fix" for patients, while the iCAST stent was a "long-term fix." Based on this training, Ms. Sullivan made these representations to VA physicians in Durham, North Carolina, including Dr. Richard McCann, Dr. Leila Mureebe, Dr. Mike Miller, and Dr. Toby Smith. She also heard John Schindler make similar representations to VA physicians. Ms. Sullivan told the same thing to Dr. Ryan Theumy and Dr. William Bozeman at Womack Army Hospital in North Carolina. Later, when Ms. Sullivan told the same thing to Dr. Kimberley Hansen, the Chief of the Department of Vascular and Endovascular Surgery at Wake Forest School of Medicine, he laughed and told her, "I don't know what Atrium is telling you, but they're wrong." In other words, Atrium was instructing its sales people to misrepresent studies or repeat statements that had no basis in fact to physicians, including Government-employed physicians, in order to persuade them to pay for Atrium's expensive iCAST stents. Ms. Sullivan believes that many physicians, including those employed at the VA and Womack Army Hospital, who were falsely told that the iCAST works long-term, while bare metal stents do not, purchased and used iCAST stents because of these misrepresentations. She recalls that after making these statements to physicians, they chose to purchase and implant iCAST stents.

D. ATRIUM'S GUIDANCE TO PHYSICIANS ABOUT MEDICARE CODING FOR UNAPPROVED USES

52. Because the iCAST stent was not approved for use in the vascular system, physicians often expressed concern to Ms. Sullivan and her fellow sales reps about how to code for payment the unapproved use of the device. In about 2010, Jonathan Berry, a cardiologist at Moses H. Cone Memorial Hospital in Greensboro, North Carolina, contacted Ms. Sullivan with some concern about how to bill a procedure in which the iCAST was placed in the peripheral vascular arteries. After contacting Mike Dupont in Hudson, N.H., the company headquarters

about the concern, Mr. Dupont verbally gave her the coding information fro the Viabhan stent from the Gore website, and sent the same code by text to her Blackberry device. Ms. Sullivan was instructed to provide it to Dr. Berry. Thereafter, Mike Dupont, Pat Racanelli and Brian Oakes, Ms. Sullivan's manager, all circulated an e-mail to sales reps circulating a coding guide that they had pulled off of the Gore Viabahn website that they then manipulated to look like an Atrium coding guide, by inserting the Atrium logo above the code they had taken from the Gore site. Dupont, Racanelli, and Oakes instructed their sales reps to print the guide and have it laminated so that they could use it to coach the physicians as to how to code for reimbursement of unapproved uses of the iCAST stents. In addition to providing the "guide" to Dr. Berry, Ms. Sullivan used this "guide" to coach the following physicians on coding for reimbursement:

Dr. Robert Albrecht, First Health Moore Regional, Pinehurst, NC

Dr. Richard Edrington, Rex Hospital, Raleigh, NC

Dr. Ravish Sachar, Wake Forest Medical School, Raleigh, NC

Dr. Maurice Roulhac, Cape Fear Valley Hospital, Fayetteville, NC

Dr. Mohit Pasi, Rex Hospital, Raleigh, NC

Dr. David Peterson, Wake Med Medical Center, Raleigh, NC

Dr. Byron Abels, Rex Hospital, Raleigh, NC

Dr. Jay Ganji, Moses H. Cone Memorial Hospital, Greensboro, NC

Dr. William Bell, Carolina Medical Hospital, New Bern, NC

Dr. David Weatherford, New Hanover Regional Hospital, Wilmington, NC

53. This coding document was distributed by regional managers and training personnel throughout the company to sales reps across the country for use with their accounts.

E. MISBRANDING

54. Although Atrium guided physicians on how to have procedures in which the iCAST was used paid for by Medicare, it did not provide proper written instructions for any uses of the iCAST stent besides for tracheobronchial procedures. The instructions that accompanied the iCAST stent, which were and had to be cleared by the FDA, specifically provide guidance to physicians about how to use the stent in tracheobronchial procedures. For example, the "Instructions for Use" refer to the use of a bronchoscope and endotracheal tube with the iCAST. The cleared instructions also state that expansion of the stent should not be undertaken if it is not "appropriately positioned in the tracheal." There are no instructions in the Instructions for Use for positioning the iCAST stent in the iliac, carotid, or renal arteries, for example. And there are no warnings about using the iCAST in the iliac, carotid, or renal arteries.

55. Federal regulations require all medical devices to contain adequate directions for use. For prescription devices to be marketed, they must include labeling "on or within the package from which the device is to be dispensed bearing information for use, including indications, effects, routes, methods, and frequency and duration of administration, and any relevant hazards, contraindications, side effects, and precautions under which practitioners licensed by law to administer the device can use the device safely and *for the purpose for which it is intended, including all purposes for which it is advertised or represented.*" 21 C.F.R. § 801.109(c) (emphasis supplied). Moreover, any such labeling must contain "*adequate information* for such use, including indications, effects, routes, methods, and frequency and duration of administration and any relevant hazards, contraindications, side effects, and

precautions, under which practitioners licensed by law to employ the device can use the device safely and for the purposes for which it is intended, *including all purposes for which it is advertised or represented.*" *Id.* § 801.109(d) (emphasis supplied). In other words, for a device to be marketed, it must contain adequate instructions to the physician for using the device for all purposes for which it is advertised or represented. As the definition of "intended uses" makes clear, "if a manufacturer knows, or has knowledge of facts that would give him notice that a device introduced into interstate commerce by him is to be used for conditions, purposes, or uses other than the ones for which he offers it, he is required to provide adequate labeling for such a device which accords with such other uses to which the article is to be put." 21 C.F.R. § 801.4.

56. A device is considered misbranded unless its labeling bears "adequate directions for use." 21 U.S.C. § 352(f). The iCAST was misbranded, and since it failed to bear adequate instructions for its known and intended uses, was also a substandard product that the Government would not have paid for had it known that it was misbranded, substandard, and "worthless."

57. Furthermore, "[a]ny representation that creates an impression of official approval of a device because of complying with the premarket notification [510K] regulations is misleading and constitutes misbranding." 21 C.F.R. § 807.97 (emphasis added).

F. PATIENT HARM & RISKS OF UNAPPROVED USE

58. As discussed above, the FDA considers stents used in the vascular system to be high-risk devices subject to regulation as Class III devices. Indeed, throughout her time at Atrium, surgeons reported concerns and problems to Ms. Sullivan related to the unapproved use of the iCAST device.

59. For example, in March of 2009, Ms. Sullivan had a meeting with Dr. Michael Cooper, a cardiologist at the Moses H. Cone Memorial Hospital in Greensboro, MC. Michael Primich, her manager was present, and he began to explain to Dr. Cooper that most doctors were using the iCAST stent in the iliac and renal arteries. Dr. Cooper was concerned and said that placing the iCAST stent into the iliac would "gel off any collaterals and would not be good for the patients in the long term." Ms. Sullivan took this to mean that the iCAST would block the blood flow to the smaller arteries leading into the iliac artery. After Dr. Cooper expressed his concerns, Mr. Primich continued to try to persuade Dr. Cooper specifically assuring him that doctors across the country were using the iCAST device for this purpose with "great results."

60. In February 2011, Ms. Sullivan met with Dr. Andrew Hearn, a vascular surgeon in the cath lab at the Alamance Regional Medical Center in Burlington, NC. The purpose of the meeting was to discuss potential uses of the iCAST stents. Ms. Sullivan explained to Dr. Hearn that other doctors were using the stents mostly in the iliac and renal arteries. One morning shortly after the meeting, the relator received a call from Dr. Hearn about a patient for whom a procedure with the iCAST did not go well. Dr. Hearn had tried to place several iCAST stents in the patient's renal artery and the stents had come off their mount before he could get them deployed. Dr. Hearn had used several stents and wanted to report the occurrences to the company for review. Ms. Sullivan immediately called her manager, Brian Oakes, to report the issues, but he said he did not have a protocol to report any clinical issues. Oakes told Ms. Sullivan to give it some time and the doctor would forget about it.

61. This was not the first time that a physician had complained that an iCAST stent had not functioned properly when placed in an artery. In about 2007, Ms. Sullivan and Mike Dupont were called on to retrieve a stent after Dr. Mark Farber of the University of North

Carolina had to remove it when it did not deploy properly. Mike Dupont told Dr. Farber that he would have the engineers at Atrium look at the stent. Instead, he took the bio-hazard bag in which the stent had been placed, and on his way out of the facility, threw it in the trash can. Mr. Dupont told Ms. Sullivan to "give it some time" and Dr. Farber would forget about it.

62. In addition to these specific instances in which the iCAST failed to function properly when used for unapproved indications, the FDA's MAUDE database of adverse events lists at least 40 reports in the past 5 years of adverse events associated with use of the iCAST stent in the renal and iliac arteries.

G. ATRIUM'S MARKETING SCHEME VIOLATED THE FALSE CLAIMS ACT

1. FDA Approval of Medical Devices

63. The Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 et seq., regulates the approval and marketing of medical devices. No medical device may be marketed in the United States without prior approval or clearance by the FDA for its intended use. 21 U.S.C. § 360.

64. The FDCA creates three categories of devices that are subject to increasing levels of regulatory oversight: Class I (low risk, general controls), Class II (medium-risk, special controls), and Class III (high-risk, premarket approval). 21 U.S.C. § 360c(a)(1). Class III devices include those for which it is impossible to establish special regulations that assure safety, those "purported or represented to be for use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health," and those that "present[ ] a potential unreasonable risk of illness or injury." 21 U.S.C. § 360c(a)(1)(C).

65. In order to market a Class III device, a manufacturer must submit a comprehensive application to the FDA for premarket approval. 21 U.S.C. § 360e(c). The device

is approved only for its "intended uses" or "the objective intent of the persons legally responsible for the labeling of the devices." 21 C.F.R. § 801.4. The FDA must also approve any changes to the intended uses of a Class III device. 21 C.F.R. §§ 801.4, 807.81.

66. Class II devices may be cleared through a less costly and time-consuming process known as "510(k)" clearance, which allows clearance based upon prior approval of a substantially equivalent device, 21 U.S.C. § 360; 21 C.F.R. § 807.87(k).

67. To obtain 510(k) clearance to market a device, the manufacturer must submit a premarket notification, including a certified "statement that the submitter believes, to the best of his or her knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted." 21 C.F.R. § 807.87(k). The notification must include the intended uses of the device, the conditions the device is designed to treat, and the relevant patient population. 21 C.F.R. § 807.92(a)(5). By statute, the FDA must rely on a manufacturer's statement of intended use in a 510(k) premarket notification. 21 U.S.C. § 360c(i)(1)(E)(i).

68. Clearance through the 510(k) process does not "in any way" constitute FDA "approval" of the device, 21 C.F.R. § 807.97 ; it limits the cleared use of the device to those indications listed in the application as the intended uses. 21 U.S.C. § 352(f); 21 C.F.R. § 801.5; 21 C.F.R. § 807.97. These limited indications must be listed on the label, and a manufacturer may only promote a device for cleared or approved indications. 21 U.S.C. § 352(f); 21 C.F.R. § 807.81(a)(3).

69. Any promotion of a device for any indication not approved or cleared by the FDA and indicated on the label is considered an "off-label" promotion – that is, promotion for an unapproved use – and is unlawful. *See* 21 U.S.C. § 331(d). What is more, the FDA defines an

"unapproved medical device" as one which, under 21 U.S.C. § 351(f), is subject to premarket approval to provide reasonable assurance of its safety and effectiveness for the purpose, condition, or use for which it is intended" but does not have either (1) PMA approval under or (2) an Investigational Device Exemption." Guidance for the Emergency Use of Unapproved Medical Devices, 50 Fed. Reg. 42866 (Oct. 22, 1985). "In short, an unapproved device is a device that is utilized for a purpose, condition, or use for which the device ordinarily is required to have, but does not have, an approved PMA or IDE." *Id.*

70. As set forth above, Atrium committed fraud on the FDA and fraudulently induced the FDA to approve the iCAST device by representing that its intended use was as a product with substantial equivalence to a product used to treat tracheobronchial strictures when, in fact, Atrium never intended the iCAST to be used for this purpose. The FDA, believing Atrium's representations, cleared the iCAST device pursuant to the 510(k) procedure. Moreover, Atrium also committed fraud by marketing the iCAST stent for uses that were not approved by the FDA, and thus engaged in unlawful, off-label promotion of the devices, which are "unapproved devices" when used for unapproved indications.

2. Coverage for Medical Devices

71. Medicare, Medicaid, TRICARE and the VA paid for claims related to procedures and physician services associated with the unapproved uses of the iCAST devices that it should not have paid for because the use of such devices was unapproved, investigational, experimental, and has not been shown to be at least as beneficial as existing, approved devices for those uses.

72. Medicare is not permitted to pay for any expense that is not "reasonable and necessary for the diagnosis and treatment of illness or injury." 42 U.S.C. § 1395(a)(1)(a). Regulations, national coverage determinations, and local coverage determinations specify

services and devices that are covered as medically reasonable and necessary. Certain services and devices are excluded from coverage because they are not reasonable and necessary. Experimental or investigational medical devices are excluded. 42 C.F.R. § 411.15(o). An investigational device exemption must be granted by the FDA to be eligible for coverage as an investigational Category B medical device. 42 C.F.R. § 405.201(a)(2).

73. Medicare payment is not made for medical and hospital services that are related to the use of a device that is not covered because CMS determines the device is not "reasonable" and "necessary" or because it is excluded from coverage for other reasons. 42 C.F.R. § 405.207. These excluded services include all services furnished in preparation for the use of a noncovered device, services furnished contemporaneously with an necessary to the use of the noncovered device, and services furnished as necessary after-care that are incident to recovery from the implantation of the device. *Id.*

74. CMS interprets the term "reasonable and necessary" to mean that a service must be safe and effective, and not experimental or investigational. Mem. From Thomas A. Ault to All Regional Administrators, re: *Medicare Coverage of Investigational Devices* 1 (Dec. 28, 1994). In addition, Medicare's manuals expressly exclude from coverage a medical device that requires, but has not obtained, premarket approval from the FDA because the device is investigational and not established to be reasonable and necessary. *See, e.g.,* Medicare Program Integrity Manual, Chapter 13, § 13.5.1 (describing "reasonable and necessary" devices as those that are "safe and effective" and "not experimental or investigational").

75. Accordingly, FDA approval or clearance is necessary, but not sufficient, for Medicare coverage. As explained by CMS,

> Both CMS and the FDA review scientific evidence, and may review the same evidence, to make purchasing and regulatory decisions. However, CMS and its contractors make coverage determinations and the FDA conducts premarket review of products under different statutory standards and different delegated authority (67 FR 66755, November 1, 2002). Whereas the FDA must determine that a product is safe and effective as a condition of approval, CMS must determine that the product is reasonable and necessary as a condition of coverage under section 1862(a)(1)(A) of the Act. CMS adopts FDA determinations of safety and effectiveness, and CMS evaluates whether or not the product is reasonable and necessary for the Medicare population. Although an FDA-regulated product must receive FDA approval or clearance (unless exempt from the FDA premarket review process) for at least one indication to be eligible for Medicare coverage, except for Category B devices under an IDE clinical trial (*see* 60 FR 48417, September 19, 1995), . . . FDA PMA approval alone is not sufficient for making a determination concerning Medicare coverage.
>
> The same applies to FDA Premarket notification (510(k)) clearance. As we stated in 66 FR 58788, 58797 (November 23, 2001), "[t]he criteria the FDA uses in making determinations related to substantial equivalency under section 510(k) of the Food, Drug, and Cosmetic Act is significantly different from the scientific evidence considered in making a determination that a device is "reasonable and necessary" by Medicare. FDA does not necessarily require clinical data or outcomes studies for a determination of substantial equivalency for clearance of a device under section 510(k) of the Food, Drug, and Cosmetic Act. Medicare NCDs consider medical benefit and clinical utility of an item or service in determining whether the item or service is considered reasonable and necessary under the Medicare program. Thus, a Premarket notification cleared under section 510(k) of FDA is not sufficient for determination of Medicare coverage."

CMS, Decision Memo for Carotid Artery Stenting (CAG-0085R) at Section V, attached as Exhibit 2 (emphasis added).

76. In other words, devices must be either approved or cleared by the FDA *and* reasonable and necessary in order for Medicare to cover the use of the device. The only exception is for devices that are used in conjunction with certain Investigational Device Exemption (IDE) studies. This exception only applies to the use of the device within the FDA-

approved study setting, and even then, the device must be considered "reasonable and necessary." *Medicare Benefit Policy Manual*, Ch. 14, Medical Devices, Section 20. "Medicare payment is not made for medical and hospital services that are related to the use of a device that is not covered under Medicare." *Id.* at Section 40.

77. Each version of the relevant National Coverage Determination (NCD) issued by CMS from 2001 through the present addressing coverage of Percutaneous Transluminal Angioplasties ("PTA"), is attached hereto as Exhibit 3 and incorporated as if fully set forth herein. From 2001 through 2004, this NCD specified that Medicare would only cover "PTA of the carotid artery concurrent with carotid stent placement when furnished in accordance with . . . FDA approved protocols governing Category B . . . IDE clinical trials." National Coverage Determination for Percutaneous Transluminal Angioplasty 20.7, ver. 1, effective 07/01/2001-10/12/2004. Beginning on October 12, 2004, Medicare also began covering PTA of the carotid artery concurrent with carotid stent placement in FDA-approved post-approval studies, for an FDA-approved indication, and in accordance with FDA-approved protocols. *Id.*, ver. 2, effective 10/12/2012-3/17/2005. Beginning on March 17, 2005, Medicare expanded its coverage for PTA in patients at high risk for carotid endarterectomy using FDA-approved stents. *Id.*, ver. 3, effective 03/17/2005-11/06/2006. Since 2005, the NCD has specified that Medicare will only cover the use of a stent concurrent with PTA of a carotid artery where the stent is in an FDA-approved Category B IDE trials, in FDA-approved post-approval studies, or is FDA-approved. *Id.*, vers. 4-10, effective 11/06/2006-present.

78. In the absence of an NCD, federal law authorizes Medicare administrative contractors ("MACs") and fiscal intermediaries ("FIs") to issue local determinations as to whether certain conditions or services will be covered by Medicare. *See* 42 U.S.C. § 1395ff.

CMS instructs that "an item or service may be covered by a contractor LCD if . . . [i]t is reasonable and necessary under 862(a)(1)(A) of The Act. Only reasonable and necessary provisions are considered part of the LCD." Medicare Program Integrity Manual, Chapter 13, at § 13.5.1. CMS specifies that an item or service is "reasonable and necessary if the contractor determines that the services is . . . Safe and effective; Not experimental or investigational[.]" *Id.*

79. Accordingly, MACs and FIs publish local coverage determinations establishing requirements for coverage for medical devices. The MAC for the Arkansas, Louisiana, Mississippi, Colorado, Texas, Oklahoma, and New Mexico region, Novitas, for example, has issued LCD L32641 for coverage of non-coronary vascular stents. That LCD states that "as published in CMS IOM Pub. 100-08, Section 13.5.1, in order to be covered under Medicare, a service shall be reasonable and necessary." Further, "contractors shall consider a service to be reasonable and necessary if the contractor determines that the service is:

- Safe and effective
- Not experimental or investigational . . . .
- Appropriate . . . in terms of whether it is:
    - Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member.
    - Furnished in a setting appropriate to the patient's medical needs and condition.
    - Ordered and furnished by qualified personnel.
    - One that meets, but does not exceed, the patient's medical needs.
    - At least as beneficial as an existing and available medically appropriate alternative."

80. This LCD, like others listed *infra*, also makes clear that "[c]overage for non-coronary vascular stents depends on the use of an FDA-approved stent." *Id.* (emphasis added). Further, "[s]tent placement is covered by Medicare only when an FDA-approved stent is: used for the FDA-approved indications[,] Or, [u]sed for the above indications supported by the peer medical literature."

81. Additional retired and current LCDs and Local Medical Review Policies ("LMRPs") for the following states and the following time periods are attached hereto as Exhibits 4 and Exhibit 5, and are incorporated by reference as if fully set forth herein. Each specifies that only FDA approved stents are covered[4]:

	Number	States	Time Period
1	L30798	Alaska, Alabama, Arkansas, Arizona, Connecticut, Florida, Georgia, Iowa, Idaho, Illinois, Indiana, Kansas, Kentucky, Louisiana, Massachusetts, Maine, Michigan, Minnesota, Missouri (entire state), Mississippi, Montana, North Dakota, Nebraska, New Hampshire, New Jersey, Ohio, Oregon, Rhode Island, South Carolina, South Dakota, Tennessee, Utah, Virginia, Virgin Islands, Vermont, Washington, Wisconsin, West Virginia, Wyoming	07/16/2010 – present
2	L10163	Alaska, American Samoa, Arizona, Guam, Hawaii, Nevada, Oregon, Washington, Northern Marina Islands	07/01/1999 – 08/15/2005

[4] Some, however, set out the exception described in the NCD, *supra*, for investigational devices or post-approval studies with FDA-approved protocols. *See, e.g.,* L20428. Other LCDs describe the covered use of "vascular stents" for vascular procedures. The iCAST, as discussed *supra*, is not a vascular stent.

L14464	Alaska, American Samoa, Arizona, Guam, Hawaii, Nevada, Oregon, Washington, Northern Marina Islands	07/01/1999 – 08/15/2005
L16138	Arkansas	04/15/2004 – 09/29/2004
L16150	Arkansas	04/15/2004 – 08/12/2012
L32641	Arkansas	08/13/2012 – present
L10552	Colorado	07/01/1999 – 06/24/2005
L32641	Colorado, New Mexico, Oklahoma, Texas	08/13/2012 – 04/08/2015
L32641	District of Columbia, Delaware, Maryland, New Jersey, Pennsylvania	08/13/2012 – present
L32102	Florida	10/16/2011 – present
L32107	Florida	10/16/2011 – present
L10909	Illinois	12/01/1999 – 10/01/2004
L12290	Illinois	01/01/2002 – 05/31/2007
L19693	Illinois	12/01/1999 – 04/16-2008
L1805	Indiana	01/01/2002 – 05/31/2007
L7714	Indiana	10/15/2001 – 08/31/2006
L11140	Iowa	04/01/2000 – 08/15/2005
L12291	Kentucky	01/01/2002 – 05/31/2007
L7846	Kentucky	10/15/2001 – 08/22/2006
L16154	Louisiana	04/15/2004 – 08/12/2012
L32641	Louisiana	08/13/2012 – present
L1523	Louisiana, Mississippi	06/24/2002 – 07/31/2010
L33121	Louisiana, Mississippi	08/01/2010 – 08/19/2012
L11092	Michigan	12/01/1999 – 10/01/2004
L19694	Michigan	12/01/1999 – 07/16/2010
L10855	Minnesota	02/15/2003 – 10/01/2004
L32641	Mississippi	08/13/2012 – present
L22634	Missouri (entire state)	02/01/2008 – 07/16/2010
L16153	Missouri (Northeastern & Southern)	04/15/2004 – 06/01/2008
L3578	New Jersey	10/01/2000 – 01/03/2005
L16151	New Mexico	04/15/2004 – 03/01/2008
L4072	New York (upstate)	08/01/1994 – 10/01/2004
L12293	Ohio	01/01/2002 – 05/31/2007
L6944	Ohio	11/01/2009 – 06/17/2011
L26728	Oklahoma	03/01/2008 – 04/13/2009
L16152	Oklahoma	04/15/2004 – 10/31/2004
L20428	Pennsylvania	10/15/2005 – 07/24/2007
L4519	Pennsylvania	01/29/2000 – 10/14/2005
L32102	Puerto Rico	10/16/2011 – present

40	L32107	Puerto Rico, Virgin Islands	10/16/2011 – present
41	L22028	Rhode Island	02/15/2006 – 04/30/2009
42	L24899	Rhode Island	08/01/2006 – 05/31/2009
43	L31710	South Carolina	03/19/2011 – 01/16/2014
44	L28638	Texas	04/14/2009 – 08/14/2011
45	L31440	Texas	08/15/2011 – 11/18/2012
46	L32102	Virgin Islands	10/16/2011 – present
47	L8044	Wisconsin	03/01/1998 – 10/01/2004
48	L10684	Wyoming	07/01/1999 – 06/24/2005

82. In the absence of either an NCD or LCD, MACs and FIs make coverage determinations on an individualized basis. Under either an LCD or an individual claim determination, an item or service must meet all of the conditions listed in Section 13.5.1. *Id.* at § 13.3. The first requirement of Section 13.5.1 is that an item or service must be safe and effective. Atrium does not contend that iCAST has been established as safe and effective for vascular use. Further, the iCAST's label states, "The safety and effectiveness of this device for use in the vascular system have not been established and can result in serious harm and/or death." Because the iCAST has not been established to be safe and effective for vascular use, MACs and FIs are prohibited from covering the iCAST for vascular use under an LCD or an individual clam determination.

83. Ms. Sullivan believes that Medicare should not and would not have paid for the unapproved uses of the iCAST device because: (1) the iCAST has not been established to be safe and effective for use in the vascular system and Medicare rules prohibit coverage of an item or service that is not safe and effective; (2) the iCAST has not been determined to be reasonable and necessary for use in the vascular system, and Medicare rules prohibit coverage under these circumstances; and (3) the language of the both the LCDs and the Medicare manuals makes

clear that in order for Medicare to pay for such devices, they must be approved through the pre-market approval process, which iCAST stents were not. *See* Guidance for the Emergency Use of Unapproved Medical Devices, 50 Fed. Reg. 42866 (Oct. 22, 1985), *supra*; *see also United States ex rel. Colquitt v. Abbott Laboratories*, 864 F. Supp. 2d 499, 532-33 (N.D. Tex. 2012); *see also* Exhibit 1 at 7. In addition, Medicare would not cover the placement of iCAST stents outside of tracheo-bronchial procedures because such use was unapproved, experimental and investigational, the stents were not furnished in accordance with accepted standards of medical practice, they were not at least as beneficial as the existing and available medically appropriate alternative (namely, the stents that were approved through the PMA process as Class III devices for those procedures), and their use was not supported by peer medical literature.

84. There are four parts to the Medicare Program: (1) Medicare Part A is hospital insurance that covers the cost of inpatient hospital services and post-hospital nursing facility care; (2) Medicare Part B is medical insurance that covers the cost of physician services and outpatient care; (3) Medicare Part D is prescription drug coverage; and (4) Medicare Part C provides the benefits of Parts A, B, and D through a private health insurance plan, such as an HMO or PPO.

85. Through these programs, and similar ones such as Medicaid, VA, CHAMPUS, TRICARE and FEHBP that benefit the poor, veterans, military personnel, federal employees and their families (collectively "the federal programs"), providers submit claims to and are paid by the United States Government. The rules for reimbursement under most of the programs are substantially identical to those of Medicare.

86. Reimbursement for Medicare claims is made by the United States through the Department of Health and Human Services (HHS). The Centers for Medicare and Medicaid

Services (CMS) is an agency of HHS and is directly responsible for the administration of the Medicare program. CMS, in turn, contracts with private insurance carriers to administer and pay claims from the Medicare Trust Fund. 42 U.S.C. § 1395u. In this capacity, the carriers act on behalf of CMS. 42 C.F.R. § 421.5(b). These entities are called fiscal intermediaries.

87. Under Medicare Part A, CMS makes payments retrospectively (after services are rendered) to hospitals for inpatient services. Medicare enters into provider agreements with hospitals in order to establish the hospitals' eligibility to participate in the Medicare Program. However, Medicare does not prospectively contract with hospitals to provide particular services for particular patients. Any benefits derived from those services are derived solely by the patients and not by Medicare or the United States.

88. Hospitals submit claims for interim reimbursement for these services delivered to specific Medicare beneficiaries during their hospital stays. 42 C.F.R. §§ 413.1, 413.60, 413.64. Hospitals submit patient-specific claims for interim payments on a Form UB-92, also known as a Form HCA 1450.

89. The Form UB-92/Form HCA 1450 contains the following statement:

> Submission of this claim constitutes certification that the billing information as shown on the face hereof is true, accurate and complete. That the submitter did not knowingly or recklessly disregard or misrepresent or conceal material facts. The following certifications or verifications apply where pertinent to this Bill:
>
> [. . .]
>
> The submitter understands that because payment and satisfaction of this claim will be from Federal and State funds, any false statements, documents, or concealment of a material fact are subject to prosecution under applicable Federal or State Laws.

90. As a prerequisite to payment, CMS requires hospitals to submit annually a form CMS-2552, commonly known as the Hospital Cost Report. Cost Reports are the final claim that provider submits to the fiscal intermediary for items and services rendered to Medicare beneficiaries.

91. Every Hospital Cost Report contains a "Certification" that must be signed by the chief administrator of the provider or a responsible designee of the administrator.

92. The Hospital Cost Report certification page includes the following notice:

> Misrepresentation or falsification of any information contained in this cost report may be punishable by criminal, civil and administrative action, fine and/or imprisonment under federal law. Furthermore, if services identified in this report provided or procured through the payment directly or indirectly of a kickback or where otherwise illegal, criminal, civil and administrative action, fines and/or imprisonment may result.

93. And, the responsible hospital provider official is required to certify, in pertinent part:

> To the best of my knowledge and belief, it [the Hospital Cost Report] is a true, correct and complete statement prepared from the books and records of the provider in accordance with applicable instructions, except as noted. I further certify that I am familiar with the laws and regulations regarding the provisions of health care services, and that the services identified in this cost report were provided in compliance with such laws and regulations.

94. Under Medicare Part B, a physician submits a Form 1500 to Medicare or other government-run health insurance program in order to receive payment for his services associated with an inpatient procedure. That form contains the following certification: "This is to certify that the foregoing information is true, accurate and complete. I understand that payment and satisfaction of this claim will be from Federal and State funds, and that any false claims,

statements, or documents, or concealment of material fact, may be prosecuted under applicable Federal or State laws."

95. As detailed *supra*, as a result of Atrium's marketing of the iCAST for unapproved uses, physicians, including those who worked at VA Hospitals and military hospitals, used the iCAST stent for purposes not approved by the FDA and in a way that was not medically necessary and rendered use of the iCAST device experimental. In doing so, Atrium caused hospitals and physicians to submit false claims for surgical services rendered to Medicare, Medicaid and other federal program beneficiaries admitted for surgeries.

96. Moreover, as detailed *infra*, Atrium illegally induced physicians to implant medical devices at healthcare facilities, and in so doing, caused hospitals and physicians to submit false claims for surgical services rendered to Medicare, Medicaid and other federal program beneficiaries admitted for surgeries.

H. ATRIUM VIOLATED THE ANTI-KICKBACK STATUTE

1. The Federal Anti-Kickback Statute

88. The Medicare and Medicaid Patient Protection Act, also known as the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), arose out of congressional concern that the remuneration and gifts given to those who can influence health care decisions corrupts the medical decision-making process and could result in the provision of goods and services that are more expensive and/or medically unnecessary or even harmful to a vulnerable patient population. To protect the integrity of federal health care programs, Congress enacted a prohibition against the payment of kickbacks in any form. The AKS was enacted in 1972 to "provide penalties for certain practices which have long been regarded by professional organizations as unethical, as well as unlawful . . . and which contribute appreciably to the cost

of the Medicare and Medicaid programs." H.R. Rep. No. 92-231, 92d Cong., 1st Sess. 108 (1971), reprinted in 1972 U.S.C.C.A.N. 4989, 5093.

89. In 1977, Congress amended the AKS to prohibit receiving or paying "any remuneration" to induce referrals and increased the crime's severity from a misdemeanor to a felony with a penalty of $25,000 and/or five years in jail. *See* Social Security Amendment of 1972, Pub. L. No. 92-603, 241(b) and (c); 42 U.S.C. § 1320a-7b. In doing so, Congress noted that the purpose of the anti-kickback statute was to combat fraud and abuse in medical settings, which:

> [C]heats taxpayers who must ultimately bear the financial burden of misuse of funds . . . diverts from those most in need, the nation's elderly and poor, scarce program dollars that were intended to provide vitally needed quality health services . . . [and] erodes the financial stability of those state and local governments whose budgets are already overextended and who must commit an ever-increasing portion of their financial resources to fulfill the obligations of their medical assistance programs.

H.R. Rep. No. 95-393, pt. 2, at 37, reprinted in 1977 U.S.C.C.A.N. 3039, 3047.

90. In 1987, Congress again strengthened the AKS to ensure that kickbacks masquerading as legitimate transactions did not evade its reach. *See* Medicare-Medicaid Antifraud and Abuse Amendments, Pub. L. No. 95-142; Medicare and Medicaid Patient and Program Protection Act of 1987, Pub. L. No. 100-93.

91. The AKS prohibits any person or entity from knowingly and willfully offering to pay or paying any remuneration to another person to induce that person to purchase, order, or recommend any good or item for which payment may be made in whole or in part by a federal

health care program, which includes any State health program or health program funded in part by the federal government. 42 U.S.C. §§ 1320a-7b(b), 1320a-7b(f).

92. The statute provides, in pertinent part:

> [W]hoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person . . . to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program, shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.

42 U.S.C. § 1320a-7b(b). "Kickbacks" have been defined as including payments, gratuities, and other benefits paid to physicians.

93. In addition to criminal penalties, a violation of the AKS can also subject the perpetrator to exclusion from participation in federal health care programs, 42 U.S.C. § 1320a-7(b)(7), as well as civil monetary penalties of $50,000 per violation, 42 U.S.C. § 1320a-7a(a)(7), and three times the amount of remuneration paid, regardless of whether any part of the remuneration is for a legitimate purpose, 42 U.S.C. § 1320a-7a(a).

94. Concern about improper drug marketing practices prompted the Inspector General of the Department of Health and Human Services to issue a Special Fraud Alert in 1994 concerning prescription drug marketing practices that violated the AKS. *See* Special Fraud Alert: Prescription Drug Marketing Schemes, 59 Fed. Reg. 65,376 (Dec. 29, 1994). In May 2003, the Inspector General of HHS published further guidance on marketing practices which may constitute kickbacks, the *OIG Compliance Program Guidance for Pharmaceutical Manufacturers*, 68 Fed. Reg. 23731 (May 5, 2003) ("OIG Guidelines"). The OIG Guidelines address, among other things, the conflicts that may arise when a pharmaceutical manufacturer

provides educational or research funding to "entities in a position to make or influence referrals." As a general rule, grants and other payments to physicians should be made without conditions or restrictions, otherwise the arrangement becomes a forbidden quid pro quo relationship: "Manufacturers should take steps to ensure that neither they, nor their representatives, are using these activities to channel improper remuneration to physicians or others in a position to generate business for the manufacturer or to influence the content of the program." *Id.* at § II (b)(2).

95. The AKS not only prohibits outright bribes and rebate schemes, but also prohibits any payment by a medical device company to a physician that has as one of its purposes inducement of the physician to implant one of the medical device manufacturer's devices.

96. Compliance with the AKS is a precondition to participation as a health care provider under the federally-funded healthcare programs and the state Medicaid programs. In addition, compliance with the AKS is a condition of payment for claims for which Medicare or Medicaid reimbursement is sought by medical providers.

97. In March 2010, the AKS was amended to explicitly state that "a claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim for purposes of [the FCA]." Patient Protection and Affordable Care Act ("PPACA"), Pub.L. No. 111-148, 124 Stat. 119 § 6402(f) (2010) (codified as amended at 42 U.S.C. § 1320a-7b(g)). This provision applies to any service provided after July 1, 2010. *Id.*

98. From at least 2007 until the present, Atrium has violated that AKS by using "give-away" programs to enduce physicians and hospitals to purchase iCAST stents and by providing preceptorships, speaker fees, referral dinners and lavish meals to physicians to induce them to purchase and use iCAST stents, mainly for unapproved purposes.

2. Atrium Violated the AKS by Providing Free Stents to Physicians in Order to Induce them to Purchase and Use iCAST Stents

99. As discussed briefly above, Atrium remunerates its sales people by providing them with a base pay and a commission based on the number of stents they sell. Although the bonus structure has changed throughout the years, sales reps have usually gotten somewhere between 8% and 15% commission per stent sold. Atrium managers are also paid a base salary and receive their bonus if their team reaches a certain dollar figure in sales.

100. This bonus structure often led to managers pressuring their sales people to offer "give-away" programs to physicians and hospitals in order to induce them to buy iCAST stents. For example, in about June or July of 2012, Brian Oakes, Ms. Sullivan's manager, instructed Ms. Sullivan to offer physicians, cath labs, and hospitals deals in which they would get 5 iCAST stents for free if they bought 15 iCAST stents. Specifically, Mr. Oakes instructed Ms. Sullivan to tell Dr. William Bell at Carolina Medical Center in Newburn, NC, that if he purchased 15 iCAST stents by the end of the month, he would get 5 iCAST stents for free. Mr. Oakes instructed Ms. Sullivan and the other sales reps in her region to take this approach not only with physicians, but hospital purchasing managers and operating room managers. He told them to do whatever deals necessary and that Atrium would "make it happen."

101. Ms. Sullivan refused to promote her products in this manner, but she was aware that this was a company-wide practice because it was discussed during "best practice" trainings at national sales meetings. In addition, she was aware that Todd Munt, another sales rep in Knoxville, TN, had refused to engage in this practice, and his manager went behind his back and "got the deal done" with a hospital in his region. These "give-away" offers were a part of normal sales practices at Atrium from the time Ms. Sullivan began her career at the company

until the time she left. And they worked to induce physicians to buy iCAST stents. A physician or hospital that accepted such a deal could receive as much as $11,500 in free stents in return for purchasing iCAST stents.

3. Atrium Violated the AKS by Entering Into Contracts with Hospitals Through Premier, a Hospital Purchasing Organization

102. Atrium entered into certain contracts with hospitals through Premier, a purchasing organization, that Ms. Sullivan believes violates the AKS and does not fall into any safe harbor. For example, Atrium had a contract with Cape Fear Hospital through Premier under which the pricing of Atrium's graft products was divided into tiers, with better pricing going to hospitals who ensured that a certain percentage of all their grafts were Atrium grafts. For example, Tier I pricing was for a hospital not willing to make a "commitment" to ensuring a certain percentage of their inventory consisted of Atrium products. Tier II pricing, which was more favorable, went to hospitals that would commit to ensuring 51%-79% of their graft inventory was Atrium. The most favorable pricing went to "Tier IV" hospitals that not only promised that more than 80% of their graft inventory would be Atrium, but also purchased at least $100,000 worth of Atrium product a year. According to Ms. Sullivan, these Tier IV hospitals would get "special pricing," which ensured them not only discounts on graft products, but also on stents. For example, a Tier IV hospital would be given a deal in which they would get an extra $100 off grafts if they also bought $45,000 in stents.

103. In sum, under this contract, hospitals received deep discounts on Atrium graft products if they promised, in return, to ensure a certain percentage of their stock was Atrium. Ms. Sullivan is aware that other hospitals besides Cape Fear had similar "Premier Preferred"

contracts and that, depending on the hospital, the contract could be for the duration of anywhere between one and three years.

104. Ms. Sullivan believes that these Atrium/Premier contracts violate the Anti-Kickback Statute and therefore the FCA. In *United States ex rel. Schmidt*, 386 F.3d 235 (3rd Cir. 2004), the Third Circuit found that similar contracts that Zimmer had through Premier with hospitals violated the AKS

105. Remunerations based on the volume of products sold or purchased raise concerns under the AKS. *See, e.g., Zimmer, Inc. v. Nu Tech Medical, Inc.*, 54 F. Supp. 2d 850, 854 (N.D. Ill. 1999). In this instance, Ms. Sullivan believes that the contracts at issue violate the AKS because the discounts (which count as remuneration) are based on a preset annual percentage of device purchases. The preset minimum volume requirement has the unlawful effect of "locking in" healthcare providers, increasing the potential for overutilization and interfering with the provider's normal cost and quality considerations in ordering specific goods or services. Moreover, the contracts also lock in the providers' medical staff physicians, by requiring each physician to ensure that a certain percentage of her surgeries are done with Atrium grafts. In fact, Ms. Sullivan often had physicians complain to her about the contracts because they felt as if they were not being given the opportunity to choose what was best for their patients.

106. The volume-based remuneration also violates the AKS because the remuneration causes an impermissible shift in market share. The fact that purchasers of identical numbers of Atrium grafts can receive materially different discounts lays bare the predatory nature of the Atrium/Premier hospital contracts. The price reductions are based on considerations other than costs, and are thus suspect and unlawful.

107. Finally, Ms. Sullivan does not believe that all of these contracts and especially the deals that were negotiated with Tier IV hospitals fell into any safe harbor of the AKS. Specifically, the AKS safe harbor with respect to discounts makes clear that the term discount does not include "supplying one good or service without charge or at a reduced charge to induce the purchase of a different good or service, unless the goods and services are reimbursed by the same Federal health care program using the same methodology and the reduced charge is fully disclosed to the Federal health care program and accurately reflected where appropriate, to the reimbursement methodology." 42 C.F.R. § 1001.952(h)(5)(ii). As set forth above, Ms. Sullivan is aware that Atrium often had contracts and deals with hospitals to supply one good or service without charge or at a reduced charge to induce the purchase of a different good or service. While she does not know whether these arrangements were disclosed to the Federal health care program, she does know that the invoices provided from Atrium to the hospitals did not list prices. Moreover, she is aware that on some occasions, the items provided without charge would be provided to the hospitals from sales reps' "personal stashes," and therefore would not be invoiced at all.

4. Atrium Violated the AKS by Paying for Preceptorships, Speaker Fees, Referral Dinners, and Lavish Meals for Physicians in Order to Induce them to Purchase and Use iCAST Stents

108. Atrium also sought to remunerate physicians for purchasing and using iCAST stents by paying them to act as trainers and speakers for the company, by paying them for preceptorships, in which the Company remunerated physicians for allowing sales reps to shadow them, by setting up referral dinners intended to provide physicians with more business, and by treating them to lavish dinners that had no educational purpose. Atrium also provided grants to certain hospitals, conditioning the grants on the purchase of iCAST stents.

109. Atrium paid certain physicians fees for training other physicians to use iCAST stents for unapproved uses. During training sessions, the training physician would be paid an honorarium to do the training, and the physicians who attended would have their airfare, hotel costs, and expenses covered by Atrium. The honoraria paid to trainers was not set by the company based on any fair market rate analysis. Instead, Atrium negotiated with the trainers on their fees, paying them amounts that represented more than fair market value for their services.

110. Atrium also paid physicians to speak at dinners and other events. Atrium only allowed physicians who used a lot of the iCAST stent to act as speakers. Again, the speaking fees were not set, but were negotiated with the physician. A sales rep would often tell a physician she would see how much she could get for her to speak. Physicians were paid between $1,500 and $3,500 to speak at events. All of these speakers discussed unapproved uses of the iCAST stent. One such speaker was Dr. Craig Walker, President & Medical Director of the Cardiovascular Institute of the South. Atrium paid him about $3,500 for each event at which he spoke, and he often spoke about unapproved uses of the iCAST, including placement in the renal and iliac arteries.

111. Atrium also trained its sales reps to organize referral dinners in which Atrium would sponsor and pay for dinners for physicians who were looking to increase their implantation practice and invite referral sources for that physician. Ms. Sullivan recalls that Pat Racanelli was employing this practice widely, and was asked by Atrium to give a presentation to other sales reps as to this "best practice." Ms. Sullivan set up one such dinner for Dr. Albrick, Dr. Atkinson, and Dr. Berman at First Health Moore Regional Hospital in Pinehurst, NC. She invited nephrologists from Cape Fear Valley Hospital. After this, First Health Moore Regional

hospital went from an account that had not bought any iCAST stents to buying $300,000 worth of iCAST stents per year.

112. Atrium also trained its sales reps to provide lavish dinners and meals to physicians in order to induce them to purchase and use iCAST stents. Atrium did not limit sales reps' budgets in any way; they were allowed to spend as much as they wanted. In addition, Ms. Sullivan's manager told her that if a dinner went above $125/person—the limit set by the medical device industry's AdvaMed guidelines—she should just add another name to her expense form so that it looked like more people attended than actually had and so that the per-person amount would be lower.

113. Atrium encouraged its sales force to take physicians to dine wherever the physicians wanted. Ms. Sullivan recalls taking physicians for dinners at Ruth's Chris steakhouse and buying $200 bottles of wine. Atrium told its sales reps that "Atrium had to be mentioned" at the dinner in order for the dinner to count as a legitimate business expense, but the dinners never had a formal educational component.

114. Ms. Sullivan's early job reviews also indicate that she was instructed by the company to set up preceptorships with physicians, in which Atrium paid physicians to have a sales rep from the company shadow them. These preceptorships served as a means to funnel money to the physicians. Ms. Sullivan does not recall doing many of these preceptorships, and believes that the practice stopped soon after she arrived at Atrium.

5. Atrium Violated the AKS by Conditioning Grants to Hospitals on Purchasing Numbers

115. Finally, Atrium provided grants to hospitals, conditioned on the purchase of iCAST stents. For example, Atrium sponsored a vascular fellowship at Duke University for

$40,000/year and a clinical investigation trial at Wake Forest University Hospital, in Winston Salem, NC. Although these grants were ostensibly provided for legitimate purposes, Chad Carlton told Ms. Sullivan that Atrium would only provide grant monies and clinical investigation trials to organizations that purchased a sufficient quantity of iCAST stents or other medical devices from Atrium, and that in many cases, as soon as the company believed that an entity was not purchasing sufficient numbers of stents, it would pull the funding.

116. For example, in 2008, Ms. Sullivan learned that Atrium was sponsoring a clinical trial at Wake Forest University Hospital in Winston Salem, NC. Clinical trials are expensive and the facility overseeing them hires personnel and also receives some of the money directly to pay for time and costs. The trial in this case involved the use of iCAST stents in the iliac artery. On Sept. 3, 2008, several months after the initial phase of the trial and funding had begun, Ms. Sullivan attended a meeting at the hospital that included the Chief of Vascular Surgery, Kimberley Hansen. Also at the meeting was Matthew S. Edwards, Director of the Vascular Surgery Center and Kelly Oliver, a vascular technician at the hospital. In addition to Ms. Sullivan, Chad Carlton from Atrium also attended. The purpose of the meeting was to review the details of the structure of the trials that were about to begin.

117. Shortly after the meeting ended, Mr. Carlton met with Ms. Sullivan to inform her that if Wake Forest was not going to use the iCAST stent in its iliac, SMA and renal procedures, Atrium was going to pull the funding for the trial. He instructed her to set up a meeting with Dr. Hansen to confirm that the facility would use the iCAST stents and to inform him of Atrium's position on the funding. Mr. Carlton told Ms. Sullivan, "We want $200-$300 thousand a year from Wake Forest and they are barely buying $40,000 worth of our stents." Ms. Sullivan then met with Dr. Hansen, who told her that he preferred to use bare metal stents as he did not see any

advantage to the covered stents. He also noted that the iCAST cost three times more than the bare metal stents. Ultimately, Wake Forest did not increase its use of iCAST stents and Atrium discontinued its funding for the clinical trial because the Company was not making enough money from Wake Forest on the purchase of iCAST stents.

118. In 2011, Brain Suddarth, Atrium's National Sales Manager, asked Ms. Sullivan to ascertain why Duke University was not using more iCAST stents. Ms. Sullivan asked Dr. Jeffrey Lawson, Professor of Surgery and a vascular surgeon at Duke, who told her that Duke was using Gore's Viabahn stent for iliac procedures. Ms. Sullivan reported this information back to Brian Suddarth. A few days later, she received a phone call from Chad Carlton, explaining that he was planning to "pull the money for the Duke fellowship program." He went on to explain that he was not happy with Dr. Cynthia Shortell, Duke's Chief of Vascular Surgery, and the low numbers of iCAST stents the hospital was purchasing. Mr. Carlton also told Ms. Sullivan that he thought that Atrium had "gotten all the mileage from that fellowship money that we can." He told her that "it bought us some relationships in the beginning, but now it's not worth it." After this conversation, Ms. Sullivan spoke again with Brian Suddarth, who told her that Duke's "slide" in the numbers of iCAST stents they were purchasing was not acceptable. He instructed Ms. Sullivan to go and see a few of the doctors with whom she had a good relationship and tell them that Atrium was going to pull Duke's funding.

119. Shortly thereafter, Ms. Sullivan met with Dr. Jeffrey Lawson, explained the situation to him, and asked him for help in getting Duke's iCAST numbers up. Dr. Lawson responded by telling Ms. Sullivan that he was concerned that she was working for a company like Atrium and recommended that she get another job with a more reputable company. He also told Ms. Sullivan that he did not like to use the iCAST stent in iliac surgery because it was not

approved for that use, while the Viabahn stent was approved for that use and was also a better stent for the patient. When Ms. Sullivan told her manager Brian Oakes about this conversation, he advised her to try to pay Dr. Lawson to lecture for Atrium, because he believed that might "persuade" Dr. Lawson to use Atrium's iCAST stents. Specifically, Mr. Oakes told Ms. Sullivan that Dr. Lawson "is known as an industry-paid whore, so offer him a paid speaking engagement." Ms. Sullivan refused to take this route.

120. In the end, Atrium did pull the funding from Duke, although it did not specifically tell Dr. Shortell why, because Ms. Sullivan refused to and no one from management would either. Ms. Sullivan let Brian Oakes, Brian Suddarth, and Jeff Harris, who was then Atrium's Global Sales VP (he is now VP of Sales for North America), know that she believe this was a bad way to do business.

121. In sum, Atrium violated the AKS by seeking to influence physicians and hospitals to purchase iCAST stents by paying them speakers fees, sponsoring referral dinners, and treating them to lavish meals. Also in violation of the AKS, Atrium conditioned its grants and clinical trials at hospitals on the purchase of sufficient quantities of iCAST stents. When certain facilities did not purchase enough of Atrium's product, it did not hesitate to pull funding and cancel clinical trials.

I. BREADTH AND TIME FRAME OF THE FRAUD

122. Although Ms. Sullivan worked for Atrium from 2007 to 2012 and became aware of the company's nationwide, company-wide sales schemes to aggressively market and promote its products off label, she was also told by Mike Primich, Heather Andrews, Pat Racanelli, and John Schindler, all of whom had management positions at Atrium, that this is the way the company has done business for years before that. Atrium markets, promotes and sells its

products to hundreds of hospitals in every state of the Union and the relator has direct knowledge from her sales trainings and weekly sales conference calls with sales directors across the country that the fraudulent techniques described herein were in fact companywide practices. In fact, Ms. Sullivan often participated on calls with Pat Racanelli, sales manager for the Midwest Region and in charge of sales in states including Texas, Arizona, Kansas, Iowa, and Missouri, and he discussed the marketing practices described above on all of his calls.

123. Since her termination from Atrium, Ms. Sullivan has learned that Atrium continues to promote the iCAST for unapproved uses. In November of 2013, for example, she attended a VEITH symposium on vascular and endovascular issues in New York, NY, and observed Atrium promote the iCAST – under its European name, Avanta V12" – in the iliac and renal arteries on a very large television display. Similarly, in April 2014, Dr. Laila Murebee, a personal friend, commented to Ms. Sullivan that she saw an unusually large Atrium booth at VIVA, a vascular symposium. Ms. Sullivan disclosed this information, as well as other information about Atrium's of the iCAST for unapproved uses into 2013, to the United States Department of Justice and the United States Attorney's Office for the Western District of Texas in a January 2014 disclosure.

COUNT ONE
VIOLATIONS OF THE FALSE CLAIMS ACT RELATED TO UNAPPROVED & FRAUDULENT MARKETING
31 U.S.C. § 3729(a)(1)(A) and 31 U.S.C. § 3729(a)(1)(B)
[for violations on or after June 7, 2008]

31 U.S.C. § 3729(a)(1) and 31 U.S.C. § 3729(a)(2)
[for violations prior to June 7, 2008]

124. Relator, acting in the name of and on behalf of the United States, restates and realleges the allegations contained in the preceding paragraphs as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

125. This is a claim for treble damages and penalties under the False Claims Act, 31 U.S.C. §§ 3729 *et seq.*, as amended.

126. By virtue of the acts described herein, Defendants knowingly presented, or caused to be presented, to officers, employees or agents of the United States under the Federal Payer Programs, false or fraudulent claims for payment or approval, and made, used and caused to be made and used false records and statements material to false claims for the medical devices illegally promoted and marketed for unapproved uses. Defendants knew that these claims for payment were false, fraudulent, or fictitious, or were deliberately ignorant of the truth or falsity of the claims, or acted in reckless disregard of whether the claims were true or false.

127. Each claim for payment for the unapproved use of the devices constitutes a false or fraudulent claim because the devices were adulterated and misbranded and not covered by the Federal Payer Programs.

128. Each claim for payment for the unapproved use of the devices constitutes a false or fraudulent claim because the devices were investigational, were not at least as beneficial as an existing and available medically appropriate alternative, were not supported by peer medical literature and/or were not covered by the Federal Payer Programs.

129. Each claim for payment for the unapproved use of the devices constitutes a false or fraudulent claim because the devices were adulterated for failing to comply with CGMP requirements.

130. Each claim for payment for the unapproved use of the devices constitutes a false or fraudulent claim because the FDA was fraudulently induced into clearing the device for a purpose for which Atrium never intended it to be marketed or used. Had the FDA known Atrium's true purpose, it would not have cleared the device to enter into the stream-of-commerce as a Class II device pursuant to the 510(k) clearance procedures.

131. Each claim for payment for implantation of the device by a physician at a government-owned entity that implanted the device due to fraudulent misrepresentations made about the device constitutes a false or fraudulent claim for which the government would not have paid had it known physicians in its employ had been misled about the safety, efficacy, and other features of the device.

132. Unaware of the falsity of the records, statements and claims made or caused to be made by Defendants, and in reliance on the truthfulness and accuracy of certifications made by physicians and hospitals, the United States paid and continues to pay on the claims that would not have been paid but for Defendants' wrongful actions and omissions.

133. The United States has been damaged, and continues to be damaged, in substantial amounts to be determined at trial. The Federal Payer Programs have paid significant amounts for the devices based on Defendants' marketing of the devices for unapproved uses.

COUNT TWO
VIOLATIONS OF THE FALSE CLAIMS ACT RELATED TO VIOLATIONS OF THE ANTI-KICKBACK STATUTE
31 U.S.C. § 3729(a)(1)(A) and 31 U.S.C. § 3729(a)(1)(B)
[for violations on or after June 7, 2008]

31 U.S.C. § 3729(a)(1) and 31 U.S.C. § 3729(a)(2)
[for violations prior to June 7, 2008]

134. Relator re-alleges and incorporates the allegations in the preceding paragraphs as if fully set forth herein.

135. Defendants' payment of kickbacks to physicians violated the AKS and other statutes and regulations controlling the payment of governmental employees and military personnel as well as payments relating to the provision of healthcare. Defendant's payment of kickbacks caused false claims and false statements to be submitted to the federal government. Since the AKS is a critical provision of Medicaid and Medicare, compliance with it is material to the government's treatment of claims for reimbursement. Had the United States and the several states known that individuals were implanted with iCAST stents because physicians and hospitals had been paid kickbacks by Defendants, neither the United States nor the States would have provided reimbursement for these implantations. As the United States and the States were unaware of the illegality of the claims, and in reliance on the accuracy and legality thereof, made payment upon the false or fraudulent claims, the United States and the States were damaged.

136. The False Claims Act, 31 U.S.C. § 3729(a)(1) and (2) (2008) and 31 U.S.C. § 3729(a)(1)(a) & (b) (2009) imposes liability upon those who knowingly cause to be presented false claims for payment or approval or who knowingly cause to be presented false statements or records to get claims paid.

137. Defendants knowingly and deliberately engaged in a concerted campaign to induce physicians to implant their medical products by paying illegal kickbacks. Claims for payment to federally-financed healthcare systems, including Medicaid, Medicare and TRICARE, resulting from defendants' purposeful, illegal kickback campaign were false claims.

138. Defendants caused these false claims to be presented to Medicare, Medicaid, and TRICARE for payment, in violation of 31 U.S.C. § 3729(a)(1) (2008) and 31 U.S.C. § 3729(a)(1)(a) (2009).

139. In addition, because violations of the AKS are material to payment by Medicare, Medicaid, and TRICARE, the representations both hospitals and physicians made on cost reports and forms submitted to Medicare associated with the implantation procedures were false or fraudulent. Thus, defendants' conduct also caused the submission of a "false record or statement to get a false or fraudulent claim paid" in violation of 31 U.S.C. § 3729(a)(2) (2008) and caused "to be made or used, a false record or statement material to a false or fraudulent claim" in violation of 31 U.S.C. § 3729(a)(1)(b).

PRAYER FOR RELIEF UNDER THE FEDERAL FALSE CLAIMS ACT

Relator respectfully requests this Court to enter judgment against defendants, as follows:

(a) That the United States be awarded damages in the amount of three times the damages sustained by the United States because of the false claims and fraud alleged within this Complaint, as the Civil False Claims Act, 31 U.S.C. §§ 3729 *et seq.* provides;

(b) That civil penalties of $11,000 be imposed for each and every false claim that defendants presented or caused to be presented to the United States;

(c) That pre- and post-judgment interest be awarded, along with reasonable attorneys' fees, costs, and expenses which the Relator necessarily incurred in bringing and pressing this case;

(d) That the Court grant permanent injunctive relief to prevent any recurrence of violations of the False Claims Act for which redress is sought in this Complaint;

(e) That the Relator be awarded the maximum percentage of any recovery allowed to her pursuant the False Claims Act, 31 U.S.C. §3730(d)(1),(2);

(f) That this Court award such other and further relief as it deems proper.

COUNT THREE

VIOLATIONS OF THE ARKANSAS MEDICAID FRAUD FALSE CLAIMS ACT

140. Relator re-alleges and incorporates the allegations in the preceding paragraphs as if fully set forth herein. Additionally, Relator states that the course of conduct described in this Complaint was a nationwide practice of Atrium Medical Corporation. Atrium Medical Corporation conducts business in the State of Arkansas. Upon information and belief, Defendants' actions described herein occurred in the State of Arkansas as well.

141. This is a qui tam action brought by Relator and the State of Arkansas to recover treble damages and civil penalties under the Arkansas Medicaid Fraud False Claims Act, A.C.A. § 20-77-901 et seq.

142. The Arkansas Medicaid Fraud False Claims Act § 20-77-902 provides liability for any person who-

> Knowingly makes or causes to be made any false statement or representation of a material fact in any application for any benefit or payment under the Arkansas Medicaid program;
>
> At any time knowingly makes or causes to be made any false statement or representation of a material fact for use in determining rights to a benefit or payment;

143. In addition, A.C.A. § 20-77-902(7)(A) prohibits soliciting, accepting, or agreeing to accept any type of remuneration for the following:

> Recommending the purchase, lease, or order of any good, facility, service, or item for which payment may be made under the Arkansas Medicaid program.

144. Defendants violated the Arkansas Medicaid Fraud False Claims Act § 20-77-902(1) (2) & (7)(A) by engaging in the fraudulent and illegal practices described herein.

145. Defendants furthermore violated Arkansas Medicaid Fraud False Claims Act § 20-77-902(1) & (2) and knowingly caused thousands of false claims to be made, used and presented to Arkansas by its violation of federal and state laws, including A.C.A. § 20-77-902(7)(A) and the AKS, as described herein.

146. Arkansas, by and through the Arkansas Medicaid program and other state health care programs, and unaware of Defendants' fraudulent and illegal practices, paid the claims submitted by health care providers and third payers in connection therewith.

147. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to Arkansas in connection with Defendants' fraudulent and illegal practices.

148. Had Arkansas known that Defendants were violating the federal and state laws cited herein, it would not have paid the claims submitted by health care providers and third party payers in connection with Defendants' fraudulent and illegal practices.

149. As a result of Defendants' violations of § 20-77-902(1) (2) & (7)(A), the State of Arkansas has been damaged in an amount far in excess of millions of dollars exclusive of interest.

150. Ms. Esther Sullivan is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to A.C.A. § 20-77-911(a) on behalf of herself and the State of Arkansas.

151. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Arkansas in the operation of its Medicaid program.

152. WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the STATE OF ARKANSAS:

Three times the amount of actual damages which the State of Arkansas has sustained as a result of Defendants' fraudulent and illegal practices;

A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendants caused to be presented to the State of Arkansas;

Prejudgment interest; and

All costs incurred in bringing this action.

To RELATOR:

The maximum amount allowed pursuant to A.C.A. § 20-77-911(a) and /or any other applicable provision of law;

Reimbursement for reasonable expenses which Relator incurred in connection with this action;

An award of reasonable attorneys' fees and costs; and

Such further relief as this court deems equitable and just.

COUNT FOUR

VIOLATIONS OF THE CALIFORNIA FALSE CLAIMS ACT

153. Relator re-alleges and incorporates the allegations in the preceding paragraphs as if fully set forth herein. Additionally, Relator states that the course of conduct described in this Complaint was a nationwide practice of Atrium Medical Corporation.

154. This is a qui tam action brought by Relator and the State of California to recover treble damages and civil penalties under the California False Claims Act, Cal. Gov't. Code § 12650 *et seq.*

155. Cal. Gov't Code § 12651(a) provides liability for any person who—

> Knowingly presents, or causes to be presented, to an officer or employee of the state of any political division thereof, a false claim for payment or approval;
>
> Knowingly makes, uses, or causes to be made or used a false record of statement to get a false claim paid or approved by the state or by any political subdivision;
>
> Conspires to defraud the state or any political subdivision by getting a false claim allowed or paid by the state of by any political subdivision.
>
> Is a beneficiary of an inadvertent submission of a false claim to the state or a political subdivision, subsequently discovers the falsity of the claim, and fails to disclose the false claim to the state or the political subdivision within a reasonable time after discovery of the false claim.

156. In addition, the payment or receipt of bribes or kickbacks is prohibited under Cal. Bus. & Prof. Code §§ 650 and 650.1, and is also specifically prohibited in treatment of Medi-Cal patients pursuant to Cal. Welf. & Inst. Code § 14107.2.

157. Defendants violated Cal Bus. & Prof. Code §§ 650 and 650.1 and Cal. Welf. & Inst. Code § 14107.2 by engaging in the fraudulent and illegal practices described herein.

158. Defendants furthermore violated Cal. Gov't Code § 12651(a) and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of California by its violation of federal and state laws, including Cal. Bus. & Prof. Code §§ 650 and 650.1 and Cal. Welf. & Inst. Code § 14107.2, and the AKS, as described herein.

159. The State of California, by and through the California Medicaid program and other state health care programs, and unaware of Defendants' fraudulent and illegal practices,

paid the claims submitted by health care providers and third party payers in connection therewith.

160. Compliance with applicable Medicare, Medi-Cal and the various other federal and state laws cited herein was implied, and upon information and belief, also an express condition of payment of claims submitted to the State of California in connection with Defendants' fraudulent and illegal practices.

161. Had the State of California known that Defendants were violating the federal and state laws cited herein, it would not have paid the claims submitted by health care providers and third party payers in connection with Defendants' fraudulent and illegal practices.

162. As a result of Defendants' violations of Cal. Gov't Code § 12651(a), the State of California has been damaged in an amount far in excess of millions of dollars exclusive of interest.

163. Ms. Esther Sullivan is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Cal. Gov't Code § 12652(c) on behalf of herself and the State of California.

164. This Court is requested to accept supplemental jurisdiction over this related state claim as it is predicated upon the same exact facts as the federal claim, and merely asserts separate damages to the State of California in the operation of its Medicaid program.

165. WHERFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the STATE OF CALIFORNIA:

> Three times the amount of actual damages which the State of California has sustained as a result of Defendants' fraudulent and illegal practices;

A civil penalty of up to $10,000 for each false claim which Defendants presented or caused to be presented to the State of California;

Prejudgment interest; and

All costs incurred in bringing this action.

To RELATOR:

The maximum amount allowed pursuant to Cal. Gov't Code § 12652 and /or any other applicable provision of law;

Reimbursement for reasonable expenses which Relator incurred in connection with this action;

An award of reasonable attorneys' fees and costs; and

Such further relief as this Court deems equitable and just.

COUNT FIVE

VIOLATIONS OF THE COLORADO MEDICAID FALSE CLAIMS ACT

166. Relators re-allege and incorporate the allegations in the preceding paragraphs as if fully set forth herein. Additionally, Relators state that the course of conduct described in this Complaint was a nationwide, continuous practice of Defendants. Atrium Medical Corporation conducts business in the State of Colorado. Upon information and belief, Defendants' actions described herein occurred in Colorado as well.

167. This is a qui tam action brought by Relators and the State of Colorado to recover treble damages and civil penalties under the Colorado Medicaid False Claims Act, Co. St. §§ 25.5-4-304 to 25.5-4-310 *et seq.*

168. Co. St. § 25.5-4-305 provides liability to any person who:

(a) Knowingly presents, or causes to be presented, to an officer or employee of the state a false or fraudulent claim for payment or approval;

(b) Knowingly makes, uses, or causes to be made or used a false record or statement material to a false or fraudulent claim;

(c) Has possession, custody, or control of property or money used, or to be used, by the state in connection with the "Colorado Medical Assistance Act" and knowingly delivers, or causes to be delivered, less than all of the money or property;

(d) Authorizes the making or delivery of a document certifying receipt of property used, or to be used, by the state in connection with the "Colorado Medical Assistance Act" and, intending to defraud the state, makes or delivers the receipt without completely knowing that the information on the receipt is true;

(e) Knowingly buys, or receives as a pledge of an obligation or debt, public property from an officer or employee of the state in connection with the "Colorado Medical Assistance Act" who lawfully may not sell or pledge the property;

(f) Knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the state in connection with the "Colorado Medical Assistance Act," or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the state in connection with the "Colorado Medical Assistance Act;"

(g) Conspires to commit a violation of paragraphs (a) to (f) of this subsection (1).

169. Defendants violated Co. St. § 25.5-4-305 by continuously engaging in the fraudulent and illegal practices described herein.

170. Defendants furthermore violated Co. St. § 25.5-4-305 and knowingly caused hundreds of thousands of false claims to be made, used, and presented to the State of Colorado by its continuous violation of federal and state laws, including the AKS, as described herein.

171. The State of Colorado, by and through the Colorado Medicaid Program and other state health care programs, and unaware of Defendants' fraudulent and illegal practices, paid the claims submitted by health care providers and third party payers in connection therewith.

172. Compliance with applicable Medicare, Medicaid, and the various other federal and state laws cited herein was implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Colorado in connection with Defendants' fraudulent and illegal practices.

173. Had Colorado known that Defendants were violating the federal and state laws cited herein, it would not have paid the claims submitted by health care providers and third party payers in connection with Defendants' fraudulent and illegal practices.

174. As a result of Defendants' violations of Co. St. §§ 25.5-4-304 to 25.5-4-310 *et seq.*, the State of Colorado has been damaged in an amount far in excess of millions of dollars exclusive of interest.

175. Atrium Medical Corporation did not, within thirty days after it first obtained information as to such violations, furnish such information to officials of the State responsible for investigating false claims violations, did not otherwise fully cooperate with any investigation of the violations, and have not otherwise furnished information to the State regarding the claims for reimbursement at issue.

176. Ms. Esther Sullivan is a private person with direct and independent knowledge of the allegations in this Complaint, who has brought this action pursuant to Co. St. § 25.5-4-306 on behalf of themselves and the State of Colorado.

177. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Colorado in the operation of its Medicaid program.

178. WHERFORE, Relator respectfully request this Court to award the following damages to the following parties and against Defendants:

To the STATE OF COLORADO:

Three times the amount of actual damages which the State of Colorado has sustained as a result of Defendants' fraudulent and illegal practices;

A civil penalty of up to $10,000 for each false claim which Defendants presented or caused to be presented to the State of Colorado;

Prejudgment interest; and

All costs incurred in bringing this action.

To RELATOR:

The maximum amount allowed pursuant to Co. St. § 25.5-4-305 and/or any other applicable provision of law;

Reimbursement for reasonable expenses which Relator incurred in connection with this action;

An award of reasonable attorneys' fees and costs; and

Such further relief as this Court deems equitable and just.

COUNT SIX

VIOLATIONS OF THE CONNECTICUT FALSE CLAIMS ACT

179. Relator re-alleges and incorporate the allegations in the preceding paragraphs as if fully set forth herein. Additionally, Relator state that the course of conduct described in this

Complaint was a nationwide, continuous practice of Atrium Medical Corporation. Atrium Medical Corporation conducts business in the State of Connecticut. Upon information and belief, Defendants actions described herein occurred in Connecticut as well.

180. This is a qui tam action brought by Relator and the State of Connecticut to recover treble damages and civil penalties under the Connecticut False Claims Act, C.G.S.A. §§ 17b-301 *et seq*.

181. C.G.S.A. § 17b-301a provides for liability for any persons who:

> (1) Knowingly present, or cause to be presented, to an officer or employee of the state a false or fraudulent claim for payment or approval under a medical assistance program administered by the Department of Social Services;
>
> (2) Knowingly make, use or cause to be made or used, a false record or statement to secure the payment or approval by the state of a false or fraudulent claim under a medical assistance program administered by the Department of Social Services;
>
> (3) Conspire to defraud the state by securing the allowance or payment of a false or fraudulent claim under a medical assistance program administered by the Department of Social Services;
>
> (4) Having possession, custody or control of property or money used, or to be used, by the state relative to a medical assistance program administered by the Department of Social Services, and intending to defraud the state or willfully to conceal the property, deliver or cause to be delivered less property than the amount for which the person receives a certificate or receipt;
>
> (5) Being authorized to make or deliver a document certifying receipt of property used, or to be used, by the state relative to a medical assistance program administered by the Department of Social Services and intending to defraud the state, make or deliver such document without completely knowing that the information on the document is true;
>
> (6) Knowingly buy, or receive as a pledge of an obligation or debt, public property from an officer or employee of the state relative to a medical assistance

> program administered by the Department of Social Services, who lawfully may not sell or pledge the property;
>
> (7) Knowingly make, use or cause to be made or used, a false record or statement to conceal, avoid or decrease an obligation to pay or transmit money or property to the state under a medical assistance program administered by the Department of Social Services.

182. Defendants violated C.G.S.A. § 17b-301a by continuously engaging in the fraudulent and illegal practices described herein.

183. Defendants furthermore violated C.G.S.A. § 17b-301a and knowingly caused hundreds of thousands of false claims to be made, used, and presented to the State of Connecticut by its violation of federal and state laws, including the AKS, as described herein.

184. The State of Connecticut, by and through the Connecticut Medicaid Program and other state health care programs, and unaware of Defendants' fraudulent and illegal practices, paid the claims submitted by health care providers and third party payers in connection therewith.

185. Compliance with applicable Medicare, Medicaid, and the various other federal and state laws cited herein was implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Connecticut in connection with Defendants' fraudulent and illegal practices.

186. Had Connecticut known that Defendants were violating the federal and state laws cited herein, it would not have paid the claims submitted by health care providers and third party payers in connection with Defendants' fraudulent and illegal practices.

187. As a result of Defendants' violations of C.G.S.A. § 17b-301, the State of Connecticut has been damaged in an amount far in excess of millions of dollars exclusive of interest.

188. Atrium Medical Corporation did not, within thirty days after it first obtained information as to such violations, furnish such information to officials of the State responsible for investigating false claims violations, did not otherwise fully cooperate with any investigation of the violations, and have not otherwise furnished information to the State regarding the claims for reimbursement at issue.

189. Ms. Esther Sullivan is a private persons with direct and independent knowledge of the allegations in this Complaint, who has brought this action pursuant to C.G.S.A. § 17b-301 on behalf of themselves and the State of Connecticut.

190. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Connecticut in the operation of its Medicaid program.

191. WHERFORE, Relator respectfully request this Court to award the following damages to the following parties and against Defendants:

To the STATE OF CONNECTICUT:

Three times the amount of actual damages which the State of Connecticut has sustained as a result of Defendants' fraudulent and illegal practices;

A civil penalty of up to $10,000 for each false claim which Defendants presented or caused to be presented to the State of Connecticut;

Prejudgment interest; and

All costs incurred in bringing this action.

To RELATOR:

The maximum amount allowed pursuant to C.G.S.A. 17b-301b and/or any other applicable provision of law;

Reimbursement for reasonable expenses which Relator incurred in connection with this action;

An award of reasonable attorneys' fees and costs; and

Such further relief as this Court deems equitable and just.

COUNT SEVEN

VIOLATIONS OF THE DELAWARE FALSE AND REPORTING CLAIMS ACT

192. Relator re-alleges and incorporates the allegations in the preceding paragraphs as if fully set forth herein. Additionally, Relator states that the course of conduct described in this Complaint was a nationwide practice of Atrium Medical Corporation. Atrium Medical Corporation conducts business in the State of Delaware. Upon information and belief, Defendants' actions described herein occurred in Delaware as well.

193. This is a qui tam action brought by Relator and the State of Delaware to recover treble damages and civil penalties under the Delaware Medicaid False Claims Act, 6 Del. C. § 1201 et seq.

194. 6 Del. C. § 1201 et seq. provides liability for any person who—

Knowingly presents, or causes to be presented, directly or indirectly, to an officer or employee of the Government a false or fraudulent claim for payment or approval;

> Knowingly makes, uses or causes to be made or used, directly or indirectly, a false record or statement to get a false or fraudulent claim paid or approved;
>
> Conspires to defraud the Government by getting a false or fraudulent claim allowed or paid;
>
> Knowingly makes, uses, or causes to be made or used a false record or statement to conceal, avoid, increase or decrease an obligation to pay or transmit money or property to or from the Government

195. Further, 31 Del. C. § 1005 provides that—

> It shall be unlawful for any person to offer or pay any remuneration (including any kickback, bribe or rebate) directly or indirectly, in cash or in kind to induce any other person . . . [t]o purchase, lease, order or arrange for or recommend purchasing, leasing or ordering any property, facility, service, or item of medical care or medical assistance for which payment may be made in whole or in part under any public assistance program.

196. Defendants violated 6 Del. C. § 1201 and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Delaware by its violation of federal and state laws, including 31 Del. C. §1005 and the AKS as described herein.

197. The State of Delaware, by and through the Delaware Medicaid program and other state health care programs, and unaware of Defendants' fraudulent and illegal practices, paid the claims submitted by health care providers and third party payers in connection therewith.

198. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Delaware in connection with Defendants' fraudulent and illegal practices.

199. Had the State of Delaware known that Defendants were violating the federal and state laws cited herein, it would not have paid the claims submitted by health care providers and third party payers in connection with Defendants' fraudulent and illegal practices.

200. As a result of Defendants' violations of 6 Del C. § 1201(a), the State of Delaware has been damaged in an amount far in excess of millions of dollars exclusive of interest.

201. Atrium Medical Corporation did not, within 30 days after it first obtained information as to such violations, furnish such information to officials of the State responsible for investigating false claims violations, did not otherwise fully cooperate with any investigation of the violations, and have not otherwise furnished information to the State regarding the claims for reimbursement at issue.

202. Ms. Esther Sullivan is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to 6 Del. C. § 1203(b) on behalf of herself and the State of Delaware.

203. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Delaware in the operation of its Medicaid program.

204. WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties against Defendants:

To the STATE OF DELAWARE:

Three times the amount of actual damages which the State of Delaware has sustained as a result of Defendants' fraudulent and illegal practices;

A civil penalty on not less than $5,500 and not more than $ 11,000 for each false claim which Defendants caused to be presented to the State of Delaware;

Prejudgment interest; and

All costs incurred in bringing this action.

To RELATOR:

The maximum amount allowed pursuant to 6 Del C. § 1205,and /or any other applicable provision of law;

Reimbursement for reasonable expenses which Relator incurred in connection with this action;

An award of reasonable attorneys' fees and costs; and

Such further relief as this Court deems equitable and just.

COUNT EIGHT

VIOLATION OF THE DISTRICT OF COLUMBIA PROCUREMENT REFORM AMENDMENT ACT

205. Relator re-alleges and incorporates the allegations in the preceding paragraphs as if fully set forth herein. Additionally, Relator states that the course of conduct described in this Complaint was a nationwide practice of Atrium Medical Corporation. Atrium Medical Corporation conducts business in the District of Columbia. Upon information and belief, Defendants' actions described herein occurred in the District of Columbia as well.

206. This is a qui tam action brought by Relator and the District of Columbia to recover treble damages and civil penalties under the District of Columbia Procurement Reform Amendment Act, D.C. § 2-308.13 et seq.

207. D.C. Code § 2-30814(a) provides liability for any person who-

Knowingly presents, or causes to be presented, to an officer or employee of the District a false claim for payment or approval;

Knowingly makes, uses or causes to be made or used, a false record or statement to get a false claim paid or approved by the District;

Conspires to defraud the District by getting a false claim allowed or paid by the District;

Is the beneficiary of an inadvertent submission of a false claim to the District, subsequently discovers the falsity of the claim, and fails to disclose the false claim to the District.

208. In addition, D.C. Code § 4-802(c) prohibits soliciting, accepting, or agreeing to accept any type of remuneration for the following:

Referring a recipient to a particular provider of any item or service or for which payment may be made under the District of Columbia Medicaid program; or

Recommending the purchase, lease, or order of any good, facility, service, or item for which payment may be made under the District of Columbia Medicaid Program.

209. Defendants violated D. C. Code § 4-802(c) by engaging in the fraudulent and illegal practices described herein.

210. Defendants furthermore violated D. C. Code § 2-308.14(a) and knowingly caused thousands of false claims to be made, used and presented to the District of Columbia by its violation of federal and state laws, including D. C. Code § 4-802(c) and the AKS, as described herein.

211. The District of Columbia, by and through the District of Columbia Medicaid program and other state health care programs, and unaware of Defendants' fraudulent and illegal practices, paid the claims submitted by health care providers and third payers in connection therewith.

212. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the District of Columbia is connection with Defendants' fraudulent and illegal practices.

213. Had the District of Columbia known that Defendants were violating the federal and state laws cited herein, it would not have paid the claims submitted by health care providers and third party payers in connection with Defendants' fraudulent and illegal practices.

214. As a result of Defendants' violations of D.C. Code § 2-308.14(a) the District of Columbia has been damaged in an amount far in excess of millions of dollars exclusive of interest.

215. Ms. Esther Sullivan is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to D.C. Code § 2-308.15(b) on behalf of herself and the District of Columbia.

216. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the District of Columbia in the operation of its Medicaid program.

217. WHEREFORE, Relator respectfully request this Court to award the following damages to the following parties and against Defendants:

To the DISTRICT OF COLUMBIA:

Three times the amount of actual damages which the District of Columbia has sustained as a result of Defendants' fraudulent and illegal practices;

A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendants caused to be presented to the District of Columbia;

Prejudgment interest; and

All costs incurred in bringing this action.

To RELATOR:

The maximum amount allowed pursuant to D. C. Code § 2-308.15(f) and /or any other applicable provision of law;

Reimbursement for reasonable expenses which Relator incurred in connection with this action;

An award of reasonable attorneys' fees and costs; and

Such further relief as this court deems equitable and just.

COUNT NINE

VIOLATION OF THE FLORIDA FALSE CLAIMS ACT

218. Relator re-alleges and incorporates the allegations in the preceding paragraphs as if fully set forth herein. Additionally, Relator states that the course of conduct described in this Complaint was a nationwide practice of Atrium Medical Corporation. Atrium Medical Corporation conducts business in the State of Florida. Upon information and belief, Defendants' actions described herein occurred in the State of Florida as well.

219. This is a qui tam action brought by Relator and the State of Florida to recover treble damages and civil penalties under the Florida False Claims Act, West's F.S.A. § 68.081 et seq.

220. West's F.S.A. § 68.082 provides liability for any person who-

> Knowingly presents or causes to be presented to an officer or employee of an agency a false claim for payment or approval
>
> Knowingly makes, uses, or causes to be made or used a false record or statement to get a false or fraudulent claim paid or approved by an agency
>
> Conspires to submit a false claim to an agency or to deceive an agency for the purpose of getting a false or fraudulent claim allowed or paid

221. Defendants violated West's F.S.A. § 68.082 by engaging in the fraudulent and illegal practices described herein.

222. Defendants furthermore violated West's F.S.A. § 68.082 and knowingly caused thousands of false claims to be made, used and presented to the State of Florida by its violation of federal and state laws, including the AKS, as described herein.

223. The State of Florida, by and through the State of Florida Medicaid program and other state health care programs, and unaware of Defendants' fraudulent and illegal practices, paid the claims submitted by health care providers and third payers in connection therewith.

224. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Florida in connection with Defendants' fraudulent and illegal practices.

225. Had the State of Florida known that Defendants were violating the federal and state laws cited herein, it would not have paid the claims submitted by health care providers and third party payers in connection with Defendants' fraudulent and illegal practices.

226. As a result of Defendants' violations of West's F.S.A. § 68.082 the State of Florida has been damaged in an amount far in excess of millions of dollars exclusive of interest.

227. Ms. Esther Sullivan is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to West's F.S.A. § 68.083(2) on behalf of herself and the State of Florida.

228. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Florida in the operation of its Medicaid program.

229. WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the STATE OF FLORIDA:

Three times the amount of actual damages which the State of Florida has sustained as a result of Defendants' fraudulent and illegal practices;

A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendants caused to be presented to the State of Florida;

Prejudgment interest; and

All costs incurred in bringing this action.

To RELATOR:

The maximum amount allowed pursuant to West's F.S.A. § 68.085 and /or any other applicable provision of law;

Reimbursement for reasonable expenses which Relator incurred in connection with this action;

An award of reasonable attorneys' fees and costs; and

Such further relief as this court deems equitable and just.

COUNT TEN

VIOLATION OF THE GEORGIA STATE FALSE MEDICAID CLAIMS ACT

230. Relator re-alleges and incorporates the allegations in the preceding paragraphs as if fully set forth herein. Additionally, Relator states that the course of conduct described in this Complaint was a nationwide practice of Atrium Medical Corporation. Atrium Medical Corporation conducts business in the State of Georgia. Upon information and belief, Defendants' actions described herein occurred in Georgia as well.

231. This is a qui tam action brought by Relator and the State of Georgia to recover treble damages and civil penalties under the Georgia State False Medicaid Claims Act, Ga. Code Ann. § 49-4-168 *et seq.*

232. Ga. Code Ann. § 49-4-168.1 *et seq.* provides liability for any person who—

> Knowingly presents or causes to be presented to the Georgia Medicaid program a false or fraudulent claim for payment or approval;
>
> Knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Georgia Medicaid program;
>
> Conspires to defraud the Georgia Medicaid program by getting a false or fraudulent claim allowed or paid;
>
> Knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay, repay or transmit money or property to the State of Georgia.

233. Defendants violated Ga. Code Ann. § 49-4-168.1 and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Georgia by its violation of federal and state laws, including the AKS, as described herein.

234. The State of Georgia, by and through the Georgia Medicaid program and other state health care programs, and unaware of Defendants' fraudulent and illegal practices, paid the claims submitted by health care providers and third party payers in connection therewith.

235. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Georgia in connection with Defendants' fraudulent and illegal practices.

236. Had the State of Georgia known that Defendants were violating the federal and state laws cited herein, it would not have paid the claims submitted by health care providers and third party payers in connection with Defendants' fraudulent and illegal practices.

237. As a result of Defendants' violations of Ga. Code Ann. § 49-4-168.1, the State of Georgia has been damaged in an amount far in excess of millions of dollars exclusive of interest.

238. Atrium Medical Corporation did not, within 30 days after first obtaining information as to such violations, furnish such information to officials of the State responsible for investigating false claims violations, did not otherwise fully cooperate with any investigation of the violations, and have not otherwise furnished information to the State regarding the claims for reimbursement at issue.

239. Ms. Esther Sullivan is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Ga. Code Ann., § 49-4-168.2(b) on behalf of herself and the State of Georgia.

240. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Georgia in the operation of its Medicaid program.

241. WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties against Defendants:

To the STATE OF GEORGIA:

Three times the amount of actual damages which the State of Georgia has sustained as a result of Defendants' fraudulent and illegal practices;

A civil penalty on not less than $5,500 and not more than $ 11,000 for each false claim which Defendants caused to be presented to the State of Georgia;

Prejudgment interest; and

All costs incurred in bringing this action.

To RELATOR:

The maximum amount allowed pursuant to Ga. Code Ann., § 49-4-168.2(i),and/or any other applicable provision of law;

Reimbursement for reasonable expenses which Relator incurred in connection with this action;

An award of reasonable attorneys' fees and costs; and

Such further relief as this Court deems equitable and just.

COUNT ELEVEN

VIOLATION OF THE HAWAII FALSE CLAIMS ACT

242. Relator re-alleges and incorporates the allegations in the preceding paragraphs as if fully set forth herein. Additionally, Relator states that the course of conduct described in this Complaint was a nationwide practice of Atrium Medical Corporation. Atrium Medical Corporation conducts business in the State of Hawaii. Defendants' actions described herein occurred in Hawaii as well.

243. This is a qui tam action brought by Relator and the State of Hawaii to recover treble damages and civil penalties under the Hawaii False Claims Act, Haw. Rev. Stat. § 661.21 et seq.

244. Haw. Rev. Stat. § 661-21(a) provides liability for any person who—

Knowingly presents, or causes to be presented, to an officer or employee of the state a false or fraudulent claim for payment or approval;

Knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the state;

> Conspires to defraud the state by getting a false or fraudulent claim allowed or paid; or
>
> Is a beneficiary of an inadvertent submission of a false claim to the State, who subsequently discovers the falsity of the claim, and fails to disclose the false claim to the State within a reasonable time after discovery of the false claim.

245. Defendants violated Haw. Rev. Stat. § 661.21(a) and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Hawaii by its violation of federal and state laws, including the AKS, as described herein.

246. The State of Hawaii, by and through the Hawaii Medicaid program and other state health care programs, and unaware of Defendants' fraudulent and illegal practices, paid the claims submitted by health care providers and third party payers in connection therewith.

247. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Hawaii in connection with Defendants' fraudulent and illegal practices.

248. Had the State of Hawaii known that Defendants were violating the federal and state laws cited herein, it would not have paid the claims submitted by health care providers and third party payers in connection with Defendants' fraudulent and illegal practices.

249. As a result of Defendants' violations of Haw. Rev. Stat. § 661-21(a) the State of Hawaii has been damaged in an amount far in excess of millions of dollars exclusive of interest.

250. Ms. Esther Sullivan is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Haw. Rev. Stat. § 661-25(a) on behalf of herself and the State of Hawaii.

251. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Hawaii in the operation of its Medicaid program.

252. WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the STATE OF HAWAII:

Three times the amount of actual damages which the State of Hawaii has sustained as a result of Defendants' fraudulent and illegal practices;

A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendants caused to be presented to the State of Hawaii;

Prejudgment interest; and

All costs incurred in bringing this action.

To RELATOR:

The maximum amount allowed pursuant to Haw. Rev. Stat. § 661-27 and /or any other applicable provision of law;

Reimbursement for reasonable expenses which Relator incurred in connection with this action;

An award of reasonable attorneys' fees and costs; and

Such further relief as this Court deems equitable and just.

COUNT TWELVE

VIOLATION OF THE ILLINOIS WHISTLEBLOWER REWARD AND PROTECTION ACT

253. Relator re-alleges and incorporates the allegations in the preceding paragraphs as if fully set forth herein. Additionally, Relator states that the course of conduct described in this

Complaint was a nationwide practice of Atrium Medical Corporation. Atrium Medical Corporation conducts business in the State of Illinois. Upon information and belief, Defendants' actions described herein occurred in Illinois as well.

254. This is a qui tam action brought by Relator and the State of Illinois to recover treble damages and civil penalties under the Illinois Whistleblower Reward and Protection Act, 740 ILCS 175 *et seq.*

255. 740 ILCS 175/3(a) provides liability for any person who—

> knowingly presents, or causes to be presented, to an officer or employee of the State of a member of the Guard a false or fraudulent claim for payment or approval;
>
> knowingly makes, uses, of causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State;
>
> conspires to defraud the State by getting a false or fraudulent claim allowed or paid.

256. In addition, 305 ILCS 5/8A-3(b) of the Illinois Public Aid Code (Vendor Fraud and Kickbacks) prohibits the solicitation or receipt of any remuneration, including any kickback, bribe or rebate, directly or indirectly, overtly or covertly, in cash or in kind in return for furnishing any item of service for which payment may be made in whole or in part under the Illinois Medicaid program.

257. Defendants violated 305 ILCS 5/8A-3(b) by engaging in the fraudulent and illegal practices described herein.

258. Defendants furthermore violated 740 ILCS 175/3(a) and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Illinois by their violation of federal and state laws, including 305 ILCS 5/8A-3(b) and the AKS, as described herein.

259. The State of Illinois, by and through the Illinois Medicaid program and other state health care programs, and unaware of Defendants' fraudulent and illegal practices, paid the claims submitted by health care providers and third party payers in connection therewith.

260. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Illinois in connection with Defendants' fraudulent and illegal practices.

261. Had the State of Illinois known that Defendants were violating the federal and state laws cited herein, it would not have paid the claims submitted by health care providers and third party payers in connection with Defendants' fraudulent and illegal practices.

262. As a result of Defendants' violations of 740 ILCS 175/3(a), the State of Illinois has been damaged in an amount far in excess of millions of dollars exclusive of interest.

263. Ms. Esther Sullivan is a private person with direct and independent knowledge of the allegation of this Complaint, who has brought this action pursuant to 740 ILCS 175/3(b) on behalf of herself and the State of Illinois.

264. This court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Illinois in the operation of its Medicaid program.

265. WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the STATE OF ILLINOIS:

> Three times the amount of actual damages which the State of Illinois has sustained as a result of Defendants' fraudulent and illegal practices;

A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendants caused to be presented to the State of Illinois;

Prejudgment interest; and

All costs incurred in bringing this action.

To RELATOR:

The maximum amount allowed pursuant to 740 ILCS/4(d) and/or any other applicable provision of law;

Reimbursement for reasonable expenses which Relator incurred in connection with this action;

An award of reasonable attorneys' fees and costs; and

Such further relief as this Court deems equitable and just.

COUNT THIRTEEN

VIOLATION OF THE INDIANA FALSE CLAIMS AND WHISTLEBLOWER PROTECTION ACT

266. Relator re-alleges and incorporates the allegations in the preceding paragraphs as if fully set forth herein. Additionally, Relator states that the course of conduct described in this Complaint was a nationwide practice of Atrium Medical Corporation. Atrium Medical Corporation conducts business in the State of Indiana. Upon information and belief, Defendants' actions described herein occurred in Indiana as well.

267. This is a qui tam action brought by Relator and the State of Indiana to recover treble damages and civil penalties under the Indiana False Claims and Whistleblower Protection Act, IC 5-11-5.5 *et seq.*

268. IC 5-11-5.5-2 provides liability for any person who—

(1) presents a false claim to the state for payment or approval;

(2) makes or uses a false record or statement to obtain payment or approval of a false claim from the state;

(3) with intent to defraud the state, delivers less money or property to the state than the amount recorded on the certificate or receipt the person receives from the state;

(4) with intent to defraud the state, authorizes issuance of a receipt without knowing that the information on the receipt is true;

(5) receives public property as a pledge of an obligation on a debt from an employee who is not lawfully authorized to sell or pledge the property;

(6) makes or uses a false record or statement to avoid an obligation to pay or transmit property to the state;

(7) conspires with another person to perform an act described in subdivisions (1) through (6); or

(8) causes or induces another person to perform an act described in subdivisions (1) through (6).

269. In addition, IC 12-15-24-1 & IC 12-15-24-2 prohibits the provision of a kickback or bribe in connection with the furnishing of items or services or the making or receipt of the payment under the Indiana Medicaid program.

270. Defendants violated IC 12-15-24-1 & IC 12-15-24-2 by engaging in the fraudulent and illegal practices described herein.

271. Defendants furthermore violated IC 5-11-5.5-2 and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Indiana by its violation of federal and state laws, including IC 12-15-24-1 & IC 12-15-24-2 and the AKS, as described herein.

272. The State of Indiana, by and through the Indiana Medicaid program and other state health care programs, and unaware of Defendants' fraudulent and illegal practices, paid the claims submitted by health care providers and third party payers in connection therewith.

273. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein is an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Indiana in connection with Defendants' fraudulent and illegal practices.

274. Had the State of Indiana known that Defendants were violating the federal and state laws cited herein, it would not have paid the claims submitted by health care providers and third party payers in connection with Defendants' fraudulent and illegal practices.

275. As a result of Defendants' violations of IC 5-11-5.5-2, the State of Indiana has been damaged in an amount far in excess of millions of dollars exclusive of interest.

276. Ms. Esther Sullivan is a private person with direct and independent knowledge of the allegation of this Complaint, who has brought this action pursuant to IC 5-11-5.5-4 on behalf of herself and the State of Indiana.

277. This court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Indiana in the operation of its Medicaid program.

278. WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the STATE OF INDIANA:

> Three times the amount of actual damages which the State of Indiana has sustained as a result of Defendants' fraudulent and illegal practices;

Prejudgment interest; and

All costs incurred in bringing this action.

To RELATOR:

The maximum amount allowed pursuant to IC 5-11-5.5-6 and/or any other applicable provision of law;

Reimbursement for reasonable expenses which Relator incurred in connection with this action;

An award of reasonable attorneys' fees and costs; and

Such further relief as this Court deems equitable and just.

COUNT FOURTEEN

VIOLATION OF THE IOWA FALSE CLAIMS ACT

279. Relator re-alleges and incorporates the allegations in the preceding paragraphs as if fully set forth herein. Additionally, Relator states that the course of conduct described in this Complaint was a nationwide practice of Atrium Medical Corporation. Atrium Medical Corporation conducts business in the State of Iowa. Upon information and belief, Defendants' actions described herein occurred in Iowa as well.

280. This is a qui tam action brought by Relator and the State of Iowa to recover treble damages and civil penalties under I.C.A. § 685.1, *et seq.*

281. I.C.A. § 685.2, provides liability, in relevant part, for any person who:

a. Knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval.

b. Knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim.

c. Conspires to violate any of these provisions.

282. Defendants violated IC I.C.A. § 685.2 by engaging in the fraudulent and illegal practices described herein.

283. Defendants furthermore violated I.C.A. § 685.2 and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Indiana by its violation of federal and state laws, as described herein.

284. The State of Iowa, by and through the Iowa Medicaid program and other state health care programs, and unaware of Defendants' fraudulent and illegal practices, paid the claims submitted by health care providers and third party payers in connection therewith.

285. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein is an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Iowa in connection with Defendants' fraudulent and illegal practices.

286. Had the State of Iowa known that Defendants were violating the federal and state laws cited herein, it would not have paid the claims submitted by health care providers and third party payers in connection with Defendants' fraudulent and illegal practices.

287. As a result of Defendants' violations of I.C.A. § 685.2, the State of Iowa has been damaged in an amount far in excess of millions of dollars exclusive of interest.

288. Ms. Esther Sullivan is a private person with direct and independent knowledge of the allegation of this Complaint, who has brought this action pursuant to I.C.A. § 685.3 on behalf of herself and the State of Iowa.

289. This court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Indiana in the operation of its Medicaid program.

290. WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties against Defendants:

To the STATE OF IOWA:

Three times the amount of actual damages which the State of Iowa has sustained as a result of Defendants' fraudulent and illegal practices;

Prejudgment interest; and

All costs incurred in bringing this action.

To RELATOR:

The maximum amount allowed pursuant to I.C.A. § 685.3 and/or any other applicable provision of law;

Reimbursement for reasonable expenses which Relator incurred in connection with this action;

An award of reasonable attorneys' fees and costs; and

Such further relief as this Court deems equitable and just.

COUNT FIFTEEN

VIOLATION OF THE LOUISIANA MEDICAL ASSISTANCE PROGRAMS INTEGRITY LAW

291. Relator re-alleges and incorporates the allegations in the preceding paragraphs as if fully set forth herein. Additionally, Relator states that the course of conduct described in this Complaint was a nationwide practice of Atrium Medical Corporation. Atrium Medical Corporation conducts business in the State of Louisiana. Upon information and belief, Defendants' actions described herein occurred in Louisiana as well.

292. This is a qui tam action brought by Relator and the State of Louisiana to recover treble damages and civil penalties under the Louisiana Medical Assistance Programs Integrity Law, La Rev. Stat. Ann § 437.1 et seq.

293. La. Rev. Stat. Ann. § 438.3 provides –

No person shall knowingly present or cause to be presented a false or fraudulent claim;

No person shall knowingly engage in misrepresentation to obtain, or attempt to obtain, payment from medical assistance programs funds;

No person shall conspire to defraud, or attempt to defraud, the medical assistance programs through misrepresentation or by obtaining, or attempting to obtain, payment for a false or fraudulent claim;

294. In addition, La. Rev. Stat. Ann.§ 438.2(A) prohibits the solicitation, receipt, offering or payment of any financial inducements, including kickbacks, bribes, rebates, etc., directly or indirectly, overtly or covertly, in cash or in kind, for furnishing health care goods or services paid for in whole or in part by the Louisiana medical assistance programs.

295. Defendants violated La. Rev. Stat. Ann § 438.2(A) by engaging in the fraudulent and illegal practices described herein.

296. Defendants furthermore violated La. Rev. Stat. Ann. § 438.3 and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Louisiana by their violation of federal and state laws, including La. Rev. Stat. Ann. § 438.2(A) and the AKS, as described herein.

297. The State of Louisiana, by and through the Louisiana Medicaid program and other state health care programs, and unaware of Defendants' fraudulent and illegal practices, paid the claims submitted by health care providers and third party payers in connection therewith.

298. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Louisiana in connection with Defendants' fraudulent and illegal practices.

299. Had the State of Louisiana known that Defendants were violating the federal and state laws cited herein, it would not have paid the claims submitted by health care providers and third party payers in connection with Defendants' fraudulent and illegal practices.

300. As a result of Defendants' violations of La. Rev. Stat. Ann. § 438.3 the State of Louisiana has been damaged in an amount far in excess of millions of dollars exclusive of interest.

301. Ms. Esther Sullivan is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to La. Rev. Stat. Ann. § 439.1(A) on behalf of herself and the State of Louisiana.

302. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Louisiana in the operation of its Medicaid program.

303. WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the STATE OF LOUISIANA:

Three times the amount of actual damages which the State of Louisiana has sustained as a result of Defendants' fraudulent and illegal practices;

A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendants caused to be presented to the State of Louisiana;

Prejudgment interest; and

All costs incurred in bringing this action.

To RELATOR:

The maximum amount allowed pursuant to La. Rev. Stat. § 439.4(A) and/or any other applicable provision of law;

Reimbursement for reasonable expenses which Relator incurred in connection with this action;

An award or reasonable attorneys' fees and costs; and

Such further relief as this Court deems equitable and just.

COUNT SIXTEEN

VIOLATION OF THE MASSACHUSETTS FALSE CLAIMS ACT

304. Relator re-alleges and incorporates the allegations in the preceding paragraphs as if fully set forth herein. Additionally, Relator states that the course of conduct described in this Complaint was a nationwide practice of Atrium Medical Corporation. Atrium Medical Corporation conducts business in the Commonwealth of Massachusetts. Upon information and belief, Defendants' actions described herein occurred in Massachusetts as well.

305. This is a qui tam action brought by Relator and State of Massachusetts for treble damages and penalties under Massachusetts False Claims Act, Mass. Gen. Laws Ann. Chap 12 § 5(A) et seq.

306. Mass. Gen. Laws Ann. Chap 12 § 5B provides liability for any person who—

Knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
Knowingly makes, uses, or causes to be made or used, a false record or statement to obtain payment or approval of a claim by the commonwealth or any political subdivision thereof;

> Conspires to defraud the commonwealth or any political subdivision thereof through the allowance or payment of a fraudulent claim;
>
> Is a beneficiary of an inadvertent submission of a false claim to the common wealth or political subdivision thereof, subsequently discovers the falsity of the claim, and fails to disclose the false claim to the commonwealth or political subdivision within a reason able time after discovery of the false claim.

307. In addition, Mass. Gen. Laws Ann. Chap. 118E § 41 prohibits the solicitation, receipt or offering of any remuneration, including any bribe ore rebate, directly or indirectly, overtly or covertly, in cash or in kind in return for furnishing any good, service or item for which payment may be made in whole or in part under the Massachusetts Medicaid program.

308. Defendants violated Mass. Gen. Laws Ann. Chap. 118E § 41 by engaging in the fraudulent and illegal practices described herein.

309. Defendants furthermore violated Mass. Gen. Laws Ann. Chap 12 § 5B and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Massachusetts by their violation of federal and state laws, including Mass. Gen. Laws Ann. Chap. 118E § 41 and the AKS, as described herein.

310. The State of Massachusetts, by and through the Massachusetts Medicaid program and other state health care programs, and unaware of Defendants' fraudulent and illegal practices, paid the claims submitted by health care providers and third party payers in connection therewith.

311. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Massachusetts in connection with Defendants' fraudulent and illegal practices.

312. Had the State of Massachusetts known that Defendants were violating the federal and state laws cited herein, it would not have paid the claims submitted by health care providers and third party payers in connection with Defendants' fraudulent and illegal practices.

313. As a result of Defendants' violations of Mass. Gen. Laws Ann. Chap. 12 § 5B the State of Massachusetts has been damaged in an amount far in excess of millions of dollars exclusive of interest.

314. Ms. Esther Sullivan is a private person with direct and independent knowledge of the allegations of the Compliant, who has brought this action pursuant to Mass. Gen. Laws Ann Chap. 12 § 5(c(2) on behalf of herself and the State of Massachusetts.

315. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon that exact same facts as the federal claim, and merely asserts separate damage to the State of Massachusetts in the operation of its Medicaid program.

316. WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the STATE OF MASSACHUSETTS:

Three times the amount of actual damages which that State of Massachusetts has sustained as a result of Defendants' fraudulent and illegal practices;

A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendants caused to be presented to the State of Massachusetts;

Prejudgment interest; and

All costs incurred in bringing this action.

To RELATOR:

The maximum amount allowed pursuant to Mass. Gen. Laws Ann. Chap. 12 § 5F and/or any other applicable provision of law;

Reimbursement for reasonable expenses which Relator incurred in connection with this action;

An award of reasonable attorneys' fees and costs; and

Such further relief as this Court deems equitable and just.

COUNT SEVENTEEN

VIOLATION OF THE MICHIGAN MEDICAID FALSE CLAIMS ACT

317. Relator re-alleges and incorporates the allegations in the preceding paragraphs as if fully set forth herein. Additionally, Relator states that the course of conduct described in this Complaint was a nationwide practice of Atrium Medical Corporation. Atrium Medical Corporation conducts business in Michigan. Upon information and belief, Defendants' actions described herein occurred in Michigan as well.

318. This is a qui tam action brought by Relator and State of Michigan for treble damages and penalties under Michigan Medicaid False Claim Act, M.C.L.A. 400.601 *et seq.*

319. M.C.L.A. 400.607 provides liability for any person who, among other things—

> Causes to be made or presented to an employee or officer of this state a claim under the social welfare act, Act No. 280 of the Public Acts of 1939, as amended, being sections 400.1 to 400.121 of the Michigan Compiled Laws, upon or against the state, knowing the claim to be false.
>
> Presents or causes to be made or presented a claim under the social welfare act, Act No. 280 of the Public Acts of 1939, which he or she knows falsely represents that the goods or services for which the claim is made were medically necessary in accordance with professionally accepted standards.

320. In addition, M.C.L.A. 400.604 prohibits the solicitation, receipt or offering of a kickback or bribe in connection with the furnishing of goods or services for which payment is or may be made in whole or in part pursuant to the Michigan Medicaid program.

321. Defendants violated M.C.L.A. 400.604 by engaging in the fraudulent and illegal practices described herein.

322. Defendants furthermore violated M.C.L.A. 400.607 and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Michigan by their violation of federal and state laws, including M.C.L.A. 400.604 and the AKS, as described herein.

323. The State of Michigan, by and through the Michigan Medicaid program and other state health care programs, and unaware of Defendants' fraudulent and illegal practices, paid the claims submitted by health care providers and third party payers in connection therewith.

324. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Michigan in connection with Defendants' fraudulent and illegal practices.

325. Had the State of Michigan known that Defendants were violating the federal and state laws cited herein, it would not have paid the claims submitted by health care providers and third party payers in connection with Defendants' fraudulent and illegal practices.

326. As a result of Defendants' violations of M.C.L.A. 400.607 the State of Michigan has been damaged in an amount far in excess of millions of dollars exclusive of interest.

327. Ms. Esther Sullivan is a private person with direct and independent knowledge of the allegations of the Compliant, who has brought this action pursuant to M.C.L.A. 400.610a on behalf of herself and the State of Michigan.

328. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon that exact same facts as the federal claim, and merely asserts separate damage to the State of Michigan in the operation of its Medicaid program.

329. WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the STATE OF MICHIGAN:

All damages to which the State of Michigan is entitled pursuant to M.C.L.A. 400.612;

Civil penalties for each false claim which Defendants caused to be presented to the State of Michigan;

Prejudgment interest; and

All costs incurred in bringing this action.

To RELATOR:

The maximum amount allowed pursuant to M.C.L.A. 400.610a(9) and/or any other applicable provision of law;

Reimbursement for reasonable expenses which Relator incurred in connection with this action;

An award of reasonable attorneys' fees and costs; and

Such further relief as this Court deems equitable and just.

COUNT EIGHTEEN

VIOLATION OF THE MONTANA FALSE CLAIMS ACT

330. Relator re-alleges and incorporates the allegations in the preceding paragraphs as if fully set forth herein. Additionally, Relator states that the course of conduct described in this

Complaint was a nationwide practice of Atrium Medical Corporation. Atrium Medical Corporation conducts business in Montana. Upon information and belief, Defendants' actions described herein occurred in Montana as well.

331. This is a qui tam action brought by Relator and State of Montana for treble damages and penalties under Montana False Claims Act, MT ST 17-8-401 *et seq.*

332. MT ST 17-8-403 provides liability for any person who—

> knowingly presenting or causing to be presented to an officer or employee of the governmental entity a false claim for payment or approval;
>
> knowingly making, using, or causing to be made or used a false record or statement to get a false claim paid or approved by the governmental entity;
>
> conspiring to defraud the governmental entity by getting a false claim allowed or paid by the governmental entity.

333. In addition, MT ST 45-6-313 prohibits the solicitation, receipt or offering any remuneration, including but not limited to a kickback, bribe, or rebate, other than an amount legally payable under the medical assistance program, for furnishing services or items for which payment may be made under the Montana Medicaid program.

334. Defendants violated MT ST 45-6-313 by engaging in the fraudulent and illegal practices described herein.

335. Defendants furthermore violated MT ST 17-8-403 and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Montana by their violation of federal and state laws, including MT ST 45-6-313 and the AKS, as described herein.

336. The State of Montana, by and through the Montana Medicaid program and other state health care programs, and unaware of Defendants' fraudulent and illegal practices, paid the claims submitted by health care providers and third party payers in connection therewith.

337. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Montana in connection with Defendants' fraudulent and illegal practices.

338. Had the State of Montana known that Defendants were violating the federal and state laws cited herein, it would not have paid the claims submitted by health care providers and third party payers in connection with Defendants' fraudulent and illegal practices.

339. As a result of Defendants' violations of MT ST 17-8-403 the State of Montana has been damaged in an amount far in excess of millions of dollars exclusive of interest.

340. Ms. Esther Sullivan is a private person with direct and independent knowledge of the allegations of the Compliant, who has brought this action pursuant to MT ST 17-8-406 on behalf of herself and the State of Montana.

341. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon that exact same facts as the federal claim, and merely asserts separate damage to the State of Montana in the operation of its Medicaid program.

342. WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the STATE OF MONTANA:

> Three times the amount of actual damages which that State of Montana has sustained as a result of Defendants' fraudulent and illegal practices;

A civil penalty of $10,000 for each false claim which Defendants caused to be presented to the State of Montana;

Prejudgment interest; and

All costs incurred in bringing this action.

To RELATOR:

The maximum amount allowed pursuant to MT ST 17-8-410 and/or any other applicable provision of law;

Reimbursement for reasonable expenses which Relator incurred in connection with this action;

An award of reasonable attorneys' fees and costs; and

Such further relief as this Court deems equitable and just.

COUNT NINETEEN

VIOLATION OF THE NEVADA FALSE CLAIMS ACT

343. Relator re-alleges and incorporates the allegations in the preceding paragraphs as if fully set forth herein. Additionally, Relator state that the course of conduct described in this Complaint was a nationwide practice of Atrium Medical Corporation. Atrium Medical Corporation conducts business in the State of Nevada. As set forth above, Defendants' actions described herein occurred in Nevada as well.

344. This is a qui tam action brought by Relator and the State of Nevada to recover treble damages and civil penalties under the Nevada False Claims Act, N.R.S. § 357.010 et. seq.

345. N.R.S. § 357.040(1) provides liability for any person who—

Knowingly presents or causes to be presented a false claim for payment or approval;

> Knowingly makes or uses, or causes to be made or used, a false record or statement to obtain payment or approval of a false claim;
>
> Conspires to defraud by obtaining allowance or payment of a false claim;
>
> Is a beneficiary of an inadvertent submission of a false claim and, after discovering the falsity of the claim, fails to disclose the falsity to the state or political subdivision within a reasonable time.

346. In addition, N.R.S. § 422.560 prohibits the solicitation, acceptance or receipt of anything of value in connection with the provision of medical goods or services for which payment may be made in whole or in part under the Nevada Medicaid program.

347. Defendants violated N.R.S. § 422.560 by engaging in the fraudulent and illegal practices described herein.

348. Defendants furthermore violated N.R.S. § 357.040(1) and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Nevada by their violation of federal and state laws, including N.R.S. § 422.560, and the AKS, as described herein.

349. The State of Nevada, by and through the Nevada Medicaid program and other health care programs, and unaware of Defendants' fraudulent and illegal practices, paid the claims submitted by health care providers and third party payers in connection therewith.

350. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of clams submitted to the State of Nevada in connection with Defendants' fraudulent and illegal practices.

351. Had the State of Nevada known that Defendants were violating the federal and state laws cited herein, it would not have paid the claims submitted by health care providers and third party payers in connection with Defendants' fraudulent and illegal practices.

352. As a result of Defendants' violations of N.R.S. § 357.040(1) the State of Nevada has been damaged in an amount far in excess or millions of dollars exclusive of interest.

353. Ms. Esther Sullivan is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to N.R.S. § 357.080(1) on behalf of herself and the State of Nevada.

354. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicted upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Nevada in the operation of its Medicaid program.

355. WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the STATE OF NEVADA:

Three times the amount of actual damages which the State of Nevada has sustained as a result of Defendants' fraudulent and illegal practices;

A civil penalty of not less than $2,000 and not more than $10,000 for each false claim which Defendants caused to be presented to the State of Nevada;

Prejudgment interest; and

All costs incurred in bringing this action.

To RELATOR:

The maximum amount allowed pursuant to N.R.S § 357.210 and/or any other applicable provision of law;

Reimbursement for reasonable expenses which Relator incurred in connection with this action;

An award of reasonable attorneys' fees and costs; and

Such further relief as this Court deems equitable and just.

COUNT TWENTY

VIOLATION OF THE NEW HAMPSHIRE FALSE CLAIMS ACT

356. Relator re-alleges and incorporates the allegations in the preceding paragraphs as if fully set forth herein. Additionally, Relator states that the course of conduct described in this Complaint was a nationwide practice of Atrium Medical Corporation. Atrium Medical Corporation conducts business in the New Hampshire. Upon information and belief, Defendants' actions described herein occurred in New Hampshire as well.

357. This is a qui tam action brought by Relator and State of New Hampshire for treble damages and penalties under New Hampshire False Claims Act, N.H. Rev. Stat. § 167:61-b *et seq.*

358. N.H. Rev. Stat. § 167:61-b provides liability for any person who—

> Knowingly presents, or causes to be presented, to an officer or employee of the department, a false or fraudulent claim for payment or approval.
>
> Knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the department.
>
> Conspires to defraud the department by getting a false or fraudulent claim allowed or paid.

359. Defendants violated N.H. Rev. Stat. § 167:61-b and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of New Hampshire by its violation of federal and state laws, including the AKS as described herein.

360. The State of New Hampshire, by and through the New Hampshire Medicaid program and other state health care programs, and unaware of Defendants' fraudulent and illegal practices, paid the claims submitted by health care providers and third party payers in connection therewith.

361. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of New Hampshire in connection with Defendants' fraudulent and illegal practices.

362. Had the State of New Hampshire known that Defendants were violating the federal and state laws cited herein, it would not have paid the claims submitted by health care providers and third party payers in connection with Defendants' fraudulent and illegal practices.

363. As a result of Defendants' violations of N.H. Rev. Stat. § 167:61-b, the State of New Hampshire has been damaged in an amount far in excess of millions of dollars exclusive of interest.

364. Ms. Esther Sullivan is a private person with direct and independent knowledge of the allegations of the Compliant, who has brought this action pursuant to N.H. Rev. Stat. § 167:61-c on behalf of herself and the State of New Hampshire.

365. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon that exact same facts as the federal claim, and merely asserts separate damage to the State of New Hampshire in the operation of its Medicaid program.

366. WHEREFORE, Relator respectfully request this Court to award the following damages to the following parties and against Defendants:

To the STATE OF NEW HAMPSHIRE:

Three times the amount of actual damages which that State of New Hampshire has sustained as a result of Defendants' fraudulent and illegal practices;

A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendants caused to be presented to the State of New Hampshire;

Prejudgment interest; and

All costs incurred in bringing this action.

To RELATOR:

The maximum amount allowed pursuant to N.H. Rev. Stat. § 167:61-e and/or any other applicable provision of law;

Reimbursement for reasonable expenses which Relator incurred in connection with this action;

An award of reasonable attorneys' fees and costs; and

Such further relief as this Court deems equitable and just.

COUNT TWENTY-ONE

VIOLATION OF THE NEW JERSEY FALSE CLAIMS ACT

367. Relator re-alleges and incorporates the allegations in the preceding paragraphs as if fully set forth herein. Additionally, Atrium Medical Corporation conducts business in New Jersey. Upon information and belief, Defendants' actions described herein occurred in New Jersey as well.

368. This is a qui tam action brought by Relator and State of New Jersey for treble damages and penalties under New Jersey False Claims Act, N.J.S.A. 2A:32C-1 et seq.

369. N.J.S.A. 2A:32C-3 provides liability for any person who—

Knowingly presents or causes to be presented to an employee, officer or agent of the State, or to any contractor, grantee, or other recipient of State funds, a false or fraudulent claim for payment or approval;

> Knowingly makes, uses, or causes to be made or used a false record or statement to get a false or fraudulent claim paid or approved by the State;
>
> Conspires to defraud the State by getting a false or fraudulent claim allowed or paid by the State.

370. In addition, N.J.S.A. 30:4D-17 prohibits solicitation, offers, or receipt of any kickback, rebate or bribe in connection with the furnishing of items or services for which payment is or may be made in whole or in part under the New Jersey Medicaid program, or the furnishing of items or services whose cost is or may be reported in whole or in part in order to obtain benefits or payments under New Jersey Medicaid.

371. Defendants violated N.J.S.A. 30:4D-17 by engaging in the fraudulent and illegal practices described herein.

372. Defendants furthermore violated N.J.S.A. 2A:32C-3 and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Nevada by their violation of federal and state laws, including N.J.S.A. 30:4D-17 and the AKS, as described herein.

373. The State of New Jersey, by and through the New Jersey Medicaid program and other state health care programs, and unaware of Defendants' fraudulent and illegal practices, paid the claims submitted by health care providers and third party payers in connection therewith.

374. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of New Jersey in connection with Defendants' fraudulent and illegal practices.

375. Had the State of New Jersey known that Defendants were violating the federal and state laws cited herein, it would not have paid the claims submitted by health care providers and third party payers in connection with Defendants' fraudulent and illegal practices.

376. As a result of Defendants' violations of N.J.S.A. 2A:32C-3 the State of New Jersey has been damaged in an amount far in excess of millions of dollars exclusive of interest.

377. Ms. Esther Sullivan is a private person with direct and independent knowledge of the allegations of the Compliant, who has brought this action pursuant to N.J.S.A. 2A:32C-5 on behalf of herself and the State of New Jersey.

378. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon that exact same facts as the federal claim, and merely asserts separate damage to the State of New Jersey in the operation of its Medicaid program.

379. WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the STATE OF NEW JERSEY:

Three times the amount of actual damages which that State of New Jersey has sustained as a result of Defendants' fraudulent and illegal practices;

A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendants caused to be presented to the State of New Jersey;

Prejudgment interest; and

All costs incurred in bringing this action.

To RELATOR:

The maximum amount allowed pursuant to N.J.S.A. 2A:32C-7and/or any other applicable provision of law;

Reimbursement for reasonable expenses which Relator incurred in connection with this action;

An award of reasonable attorneys' fees and costs; and

Such further relief as this Court deems equitable and just.

COUNT TWENTY-TWO

VIOLATION OF THE NEW YORK FALSE CLAIMS ACT

380. Relator re-alleges and incorporates the allegations in the preceding paragraphs as if fully set forth herein. Additionally, Relator state that the course of conduct described in this Complaint was a nationwide practice of Atrium Medical Corporation. Atrium Medical Corporation conducts business in the New York. As set forth above, Defendants' actions described herein occurred in New York as well.

381. This is a qui tam action brought by Relator and State of New York for treble damages and penalties under New York False Claims Act, McKinney's State Finance Law § 187 *et seq.*

382. McKinney's State Finance Law § 189 provides liability for any person who—

> Knowingly presents, or causes to be presented, to any employee, officer or agent of the state or a local government, a false or fraudulent claim for payment or approval;
>
> Knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the state or a local government;
>
> Conspires to defraud the state or a local government by getting a false or fraudulent claim allowed or paid.

383. Defendants violated § 189 by engaging in the fraudulent and illegal practices described herein.

384. Defendants furthermore violated § 189 and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of New York by their violation of federal and state laws, including the AKS, as described herein.

385. The State of New York, by and through the New York Medicaid program and other state health care programs, and unaware of Defendants' fraudulent and illegal practices, paid the claims submitted by health care providers and third party payers in connection therewith.

386. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of New York in connection with Defendants' fraudulent and illegal practices.

387. Had the State of New York known that Defendants were violating the federal and state laws cited herein, it would not have paid the claims submitted by health care providers and third party payers in connection with Defendants' fraudulent and illegal practices.

388. As a result of Defendants' violations of § 189 the State of New York has been damaged in an amount far in excess of millions of dollars exclusive of interest.

389. Ms. Esther Sullivan is a private person with direct and independent knowledge of the allegations of the Compliant, who has brought this action pursuant to McKinney's State Finance Law § 190(2) on behalf of herself and the State of New York.

390. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon that exact same facts as the federal claim, and merely asserts separate damage to the State of New York in the operation of its Medicaid program.

391. WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the STATE OF NEW YORK:

Three times the amount of actual damages which that State of New York has sustained as a result of Defendants' fraudulent and illegal practices;

A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendants caused to be presented to the State of New York;

Prejudgment interest; and

All costs incurred in bringing this action.

To RELATOR:

The maximum amount allowed pursuant to McKinney's State Finance Law § 190(6) and/or any other applicable provision of law;

Reimbursement for reasonable expenses which Relator incurred in connection with this action;

An award of reasonable attorneys' fees and costs; and

Such further relief as this Court deems equitable and just.

COUNT TWENTY-THREE

VIOLATIONS OF THE NORTH CAROLINA FALSE CLAIMS ACT

392. Relator re-alleges and incorporate the allegations in the preceding paragraphs as if fully set forth herein. Additionally, Relator state that the course of conduct described in this Complaint was a nationwide, continuous practice of Atrium Medical Corporation. Atrium Medical Corporation conducts business in the State of North Carolina. Defendants' actions described herein occurred in the State of North Carolina as well.

393. This is a qui tam action brought by Relator and the State of North Carolina to recover treble damages and civil penalties under the North Carolina False Claims Act, NC ST §§ 1-605 *et seq.*

394. NC ST § 1-607(a) provides liability for any person who:

> (1) Knowingly presents or causes to be presented a false or fraudulent claim for payment or approval;
>
> (2) Knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;
>
> (3) Conspires to commit a violation of subdivision (1), (2), (4), (5), (6), or (7) of this section;
>
> (4) Has possession, custody, or control of property or money used or to be used by the State and knowingly delivers or causes to be delivered less than all of that money or property;
>
> (5) Is authorized to make or deliver a document certifying receipt of property used or to be used by the State and, intending to defraud the State, makes or delivers the receipt without completely knowing that the information on the receipt is true.
>
> (6) Knowingly buys, or receives as a pledge of an obligation or debt, public property from any officer or employee of the State who lawfully may not sell or pledge the property.
>
> (7) Knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the State, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the State.

395. Defendants violated NC ST § 1-607(a) by engaging in the fraudulent and illegal practices described herein.

396. Defendants furthermore violated NC ST § 1-607(a) and knowingly caused thousands of false claims to be made, used, and presented to the State of North Carolina by its

continuous violation of federal and state laws, including NC ST § 1-607(a) and the AKS, as described herein.

397. The State of North Carolina, by and through the State of North Carolina Medicaid program and other state health care programs, and unaware of Defendants' fraudulent and illegal practices, paid the claims submitted by health care providers and third payers in connection therewith.

398. Compliance with applicable Medicare, Medicaid, and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of North Carolina in connection with Defendants' fraudulent and illegal practices.

399. Had the State of North Carolina known that Defendants were violating the federal and state laws cited herein, it would not have paid the claims submitted by health care providers and third party payers in connection with Defendants' fraudulent and illegal practices.

400. As a result of Defendants' violations of NC ST § 1-607(a), the State of North Carolina has been damaged in an amount far in excess of millions of dollars exclusive of interest.

401. Atrium Medical Corporation did not, within 30 days after they first obtained information as to such violations, furnish such information to officials of the State responsible for investigating false claims violations, did not otherwise fully cooperate with any investigation of the violations, and have not otherwise furnished information to the State regarding the claims for reimbursement at issue.

402. Ms. Esther Sullivan is a private persons with direct and independent knowledge of the allegations in this Complaint, who has brought this action pursuant to NC ST § 1-607(a) on behalf of themselves and the State of North Carolina.

403. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of North Carolina in the operation of its Medicaid program.

404. WHEREFORE, Relator respectfully request this Court to award the following damages to the following parties and against Defendants:

To the STATE OF NORTH CAROLINA:

Three times the amount of actual damages which the State of North Carolina has sustained as a result of Defendants' fraudulent and illegal practices;

A civil penalty of not less than $5,000 and not more than $11,000 for each false claim which Defendants caused to be presented to the State of North Carolina;

Prejudgment interest; and

All costs incurred in bringing this action.

To RELATOR:

The maximum amount allowed pursuant NC ST § 1-610 and/or any other applicable provision of law;

Reimbursement for reasonable expenses which Relator incurred in connection with this action;

An award of reasonable attorneys' fees and costs; and

Such further relief as this court deems equitable and just.

COUNT TWENTY-FOUR

VIOLATION OF THE OKLAHOMA MEDICAID FALSE CLAIMS ACT

405. Relator re-alleges and incorporates the allegations in the preceding paragraphs as if fully set forth herein. Additionally, Relator states that the course of conduct described in this Complaint was a nationwide practice of Atrium Medical Corporation. Atrium Medical

Corporation conducts business in the State of Oklahoma. Upon information and belief, Defendants' actions described herein occurred in the State of Oklahoma as well.

406. This is a qui tam action brought by Relator and the State of Oklahoma to recover treble damages and civil penalties under the Oklahoma Medicaid False Claims Act, 63 Okl. St. Ann. § 5053 *et seq.*.

407. 63 Okl. St. Ann. § 5053.1 provides liability for any person who-

> Knowingly presents, or causes to be presented, to an officer or employee of the State of Oklahoma, a false or fraudulent claim for payment or approval;
>
> Knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the state;
>
> Conspires to defraud the state by getting a false or fraudulent claim allowed or paid;

408. In addition, 56 Okl. St. Ann. § 1005 prohibits solicitation or acceptance of a benefit, pecuniary benefit, or kickback in connection with goods or services paid or claimed by a provider to be payable by the Oklahoma Medicaid Program.

409. Defendants violated 56 Okl. St. Ann. § 1005 by engaging in the fraudulent and illegal practices described herein.

410. Defendants furthermore violated 63 Okl. St. Ann. § 5053.1 and knowingly caused thousands of false claims to be made, used and presented to the State of Oklahoma by their violation of federal and state laws, including 56 Okl. St. Ann. § 1005 and the AKS, as described herein.

411. The State of Oklahoma, by and through the State of Oklahoma Medicaid program and other state health care programs, and unaware of Defendants' fraudulent and illegal

practices, paid the claims submitted by health care providers and third payers in connection therewith.

412. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Oklahoma in connection with Defendants' fraudulent and illegal practices.

413. Had the State of Oklahoma known that Defendants were violating the federal and state laws cited herein, it would not have paid the claims submitted by health care providers and third party payers in connection with Defendants' fraudulent and illegal practices.

414. As a result of Defendants' violations of 63 Okl. St. Ann. § 5053.1 the State of Oklahoma has been damaged in an amount far in excess of millions of dollars exclusive of interest.

415. Ms. Esther Sullivan is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to 63 Okl. St. Ann. § 5053.2(B) on behalf of herself and the State of Oklahoma.

416. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Oklahoma in the operation of its Medicaid program.

417. WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the STATE OF OKLAHOMA:

> Three times the amount of actual damages which the State of Oklahoma has sustained as a result of Defendants' fraudulent and illegal practices;

A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendants caused to be presented to the State of Oklahoma;

Prejudgment interest; and

All costs incurred in bringing this action.

To RELATOR:

The maximum amount allowed pursuant 63 Okl. St. Ann. § 5053.4 and /or any other applicable provision of law;

Reimbursement for reasonable expenses which Relator incurred in connection with this action;

An award of reasonable attorneys' fees and costs; and

Such further relief as this court deems equitable and just.

COUNT TWENTY-FIVE

VIOLATION OF THE RHODE ISLAND FALSE CLAIMS ACT

418. Relator re-alleges and incorporates the allegations in the preceding paragraphs as if fully set forth herein. Additionally, Relator states that the course of conduct described in this Complaint was a nationwide practice of Atrium Medical Corporation. Atrium Medical Corporation conducts business in the State of Rhode Island. Upon information and belief, Defendants' actions described herein occurred in the State of Rhode Island as well.

419. This is a qui tam action brought by Relator and the State of Rhode Island to recover treble damages and civil penalties under the Rhode Island False Claims Act, Gen. Laws 1956, § 9-1.1-1 *et seq.*

420. Gen. Laws 1956, § 9-1.1-3 provides liability for any person who-

knowingly presents, or causes to be presented, to an officer or employee of the state or a member of the guard a false or fraudulent claim for payment or approval;

> knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the state;
>
> conspires to defraud the state by getting a false or fraudulent claim allowed or paid.

421. In addition, Gen. Laws 1956, § 40-8.2-3 prohibits the solicitation, receipt, offer, or payment of any remuneration, including any kickback, bribe, or rebate, directly or indirectly, in cash or in kind, to induce referrals from or to any person in return for furnishing of services or merchandise or in return for referring an individual to a person for the furnishing of any services or merchandise for which payment may be made, in whole or in part, under the Rhode Island Medicaid program.

422. Defendants violated Gen. Laws 1956, § 40-8.2-3 by engaging in the fraudulent and illegal practices described herein.

423. Defendants furthermore violated Gen. Laws 1956, § 9-1.1-3 and knowingly caused thousands of false claims to be made, used and presented to the State of Rhode Island by their violation of federal and state laws, including Gen. Laws 1956, § 40-8.2-3 and the AKS, as described herein.

424. The State of Rhode Island, by and through the State of Rhode Island Medicaid program and other state health care programs, and unaware of Defendants' fraudulent and illegal practices, paid the claims submitted by health care providers and third payers in connection therewith.

425. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express

condition of payment of claims submitted to the State of Rhode Island in connection with Defendants' fraudulent and illegal practices.

426. Had the State of Rhode Island known that Defendants were violating the federal and state laws cited herein, it would not have paid the claims submitted by health care providers and third party payers in connection with Defendants' fraudulent and illegal practices.

427. As a result of Defendants' violations of Gen. Laws 1956, § 9-1.1-3 the State of Rhode Island has been damaged in an amount far in excess of millions of dollars exclusive of interest.

428. Ms. Esther Sullivan is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Gen. Laws 1956, § 9-1.1-4(b) on behalf of herself and the State of Rhode Island.

429. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Rhode Island in the operation of its Medicaid program.

430. WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the STATE OF RHODE ISLAND:

Three times the amount of actual damages which the State of Rhode Island has sustained as a result of Defendants' fraudulent and illegal practices;

A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendants caused to be presented to the State of Rhode Island;

Prejudgment interest; and

All costs incurred in bringing this action.

To RELATOR:

The maximum amount allowed pursuant Gen. Laws 1956, § 9-1.1-4(d) and /or any other applicable provision of law;

Reimbursement for reasonable expenses which Relator incurred in connection with this action;

An award of reasonable attorneys' fees and costs; and

Such further relief as this court deems equitable and just.

COUNT TWENTY-SIX

VIOLATION OF THE TENNESSEE FALSE CLAIMS ACT

431. Relator re-alleges and incorporates the allegations in the preceding paragraphs as if fully set forth herein. Additionally, Relator states that the course of conduct described in this Complaint was a nationwide practice of Atrium Medical Corporation. Atrium Medical Corporation conducts business in the State of Tennessee. Upon information and belief, Defendants' actions described herein occurred in Tennessee as well.

432. This is a qui tam action brought by Relator and the State of Tennessee to recover treble damages and civil penalties under the Tennessee Medicaid False Claims Act, Tenn. Code Ann. § 71-5-181 et seq.

433. Section 71-5-182(a)(1) provides liability for any person who—

Presents, or causes to be presented to the state, a claim for payment under the Medicaid program knowing such claim is false or fraudulent;

Makes or uses, or causes to be made or used, a record or statement to get a false or fraudulent claim under the Medicaid program paid for a approved by the state knowing such record or statement is false;

Conspires to defraud the State by getting a claim allowed or paid under the

Medicaid program knowing such claim is false or fraudulent.

434. Defendants violated Tenn. Code Ann. § 71-5-182(a)(1) and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Tennessee by its violation of federal and state laws, including the AKS, as described herein.

435. The State of Tennessee, by and through the Tennessee Medicaid program and other state health care programs, and unaware of Defendants' fraudulent and illegal practices, paid the claims submitted by health care providers and third party payers in connection therewith.

436. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Tennessee in connection with Defendants' fraudulent and illegal practices.

437. Had the State of Tennessee known that Defendants were violating the federal and state laws cited herein, it would not have paid the claims submitted by health care providers and third party payers in connection with Defendants' fraudulent and illegal practices.

438. As a result of Defendants' violations of Tenn. Code Ann. § 71-5-182(a)(1), the State of Tennessee has been damaged in an amount far in excess of millions of dollars exclusive of interest.

439. Ms. Esther Sullivan is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Tenn. Code Ann. § 71-5-183(a)(1) on behalf of herself and the State of Tennessee.

440. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Tennessee in the operation of its Medicaid program.

441. WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the STATE OF TENNESSEE:

Three times the amount of actual damages which the State of Tennessee has sustained as a result of Defendants' fraudulent and illegal practices;

A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendants caused to be presented to the State of Tennessee;

Prejudgment interest; and

All costs incurred in bringing this action.

To RELATOR:

The maximum amount allowed to Tenn. Code Ann. §71-5-183(c) and/or any other applicable provision of law;

Reimbursement for reasonable expenses which Relator incurred in connection with this action;

An award of reasonable attorneys' fees and costs; and

Such further relief as this Court deems equitable and just.

COUNT TWENTY-SEVEN

VIOLATION OF THE TEXAS MEDICAID FALSE CLAIMS ACT

442. Relator re-alleges and incorporates the allegations in the preceding paragraphs as if fully set forth herein. Additionally, Relator states that the course of conduct described in this Complaint was a nationwide practice of Atrium Medical Corporation. Atrium Medical Corporation conducts business in the State of Texas. Defendants' actions described herein occurred in Texas as well.

443. This is a qui tam action brought by Relator and the State of Texas to recover double damages and civil penalties under the Texas False Claims Act, V.T.C.A. Hum. Res. Code § 36.001 et seq.

444. V.T.C.A. Hum. Res. Code § 36.002, in relevant part, provides liability for any person who—

> (1) knowingly makes or causes to be made a false statement or misrepresentation of a material fact to permit a person to receive a benefit or payment under the Medicaid program that is not authorized or that is greater than the benefit or payment that is authorized;
>
> (2) knowingly conceals or fails to disclose information that permits a person to receive a benefit or payment under the Medicaid program that is not authorized or that is greater than the benefit or payment that is authorized;
>
> (3) knowingly applies for and receives a benefit or payment on behalf of another person under the Medicaid program and converts any part of the benefit or payment to a use other than for the benefit of the person on whose behalf it was received
>
> * * *
>
> (5) except as authorized under the Medicaid program, knowingly pays, charges, solicits, accepts, or receives, in addition to an amount paid under the Medicaid program, a gift, money, a donation, or other consideration as a condition to the provision of a service or product or the continued provision of a service or product if the cost of the service or product is paid for, in whole or in part, under the Medicaid program;
>
> * * *
>
> (5) except as authorized under the Medicaid program, knowingly pays, charges, solicits, accepts, or receives, in addition to an amount paid under the Medicaid program, a gift, money, a donation, or other consideration as a condition to the provision of a service or product or the continued provision of a service or product if the cost of the service or product is paid for, in whole or in part, under the Medicaid program;

* * *

> (9) knowingly enters into an agreement, combination, or conspiracy to defraud the state by obtaining or aiding another person in obtaining an unauthorized payment or benefit from the Medicaid program or a fiscal agent;
>
> * * *
>
> (12) knowingly makes, uses, or causes the making or use of a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to this state under the Medicaid program.

445. Defendants violated V.T.C.A. Hum. Res. Code § 36.002 and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Texas by their violation of federal and state laws, including, the AKS, as described herein.

446. The State of Texas, by and through the Texas Medicaid program and other state healthcare programs, and unaware of Defendants' fraudulent and illegal practices, paid the claims submitted by health care providers and third party payers in connection therewith.

447. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Texas in connection with Defendants' fraudulent and illegal practices.

448. Had the State of Texas known that Defendants were violating the federal and state laws cited herein, it would not have paid the claims submitted by health care providers and third party payers in connection with Defendants' fraudulent and illegal practices.

449. As a result of Defendants' violations of V.T.C.A. Hum. Res. Code § 36.002, the State of Texas has been damaged in an amount far in excess of millions of dollars exclusive of interest.

450. Atrium Medical Corporation did not, within 30 days after they first obtained information as to such violations, furnish such information to officials of the State responsible for investigating false claims violations, did not otherwise fully cooperate with any investigation of the violations, and have not otherwise furnished information to the State regarding the claims for reimbursement at issue.

451. Ms. Esther Sullivan is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to V.T.C.A. Hum. Res. Code § 36.101 on behalf of herself and the State of Texas.

452. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Texas in the operation of its Medicaid program.

453. WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the STATE OF TEXAS:

Damages at two times the value of any payment or monetary or in-kind benefit provided under the Medicaid program, directly or indirectly, as a result of the unlawful acts set forth above, as provided by the Texas Human Resources Code § 36.052(a)(1) & (4)

Civil penalties of $15,000 for each and every unlawful act set forth above that resulted in injury to a person younger than 18 years of age, as provided by the Texas Human Resources Code § 36.052(3)(A)

Pre- and post-judgment interest, Tex. Hum. Res. Code § 36.052(a)(2),

To RELATOR:

The maximum amount allowed pursuant to V.T.C.A. Hum Res. Code § 36.110(a), and/or any other applicable provision of law;

Reimbursement for reasonable expenses and costs which Relator incurred in connection with this action, Tex Hum Res. Code §§ 36.007 & 36.110(c);

Reasonable attorneys' fees which the Relator necessarily incurred in bringing and pressing this case, Tex Hum Res. Code §§ 36.007 & 36.110(c); and

Such further relief as this Court deems equitable and just.

COUNT TWENTY-EIGHT

VIOLATION OF THE VIRGINIA FRAUD AGAINST TAXPAYERS ACT

454. Relator re-alleges and incorporates the allegations in the preceding paragraphs as if fully set forth herein. Additionally, Relator states that the course of conduct described in this Complaint was a nationwide practice of Atrium Medical Corporation. Atrium Medical Corporation conducts business in the Commonwealth of Virginia. Upon information and belief, Defendants' actions described herein occurred in the Commonwealth of Virginia as well.

455. This is a qui tam action brought by Relator and the Commonwealth of Virginia to recover treble damages and civil penalties under the Virginia Fraud Against Taxpayers Act, Va. Code Ann. § 8.01-216.1 et seq.

456. Va. Code Ann. § 8.01-216.3 provides liability for any person who-

> Knowingly presents, or causes to be presented, to an officer or employee of the Commonwealth a false or fraudulent claim for payment or approval;
>
> Knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Commonwealth
>
> Conspires to defraud the Commonwealth by getting a false or fraudulent claim allowed or paid

457. Defendants violated Va. Code Ann. § 8.01-216.3 by engaging in the fraudulent and illegal practices described herein.

458. Defendants furthermore violated Va. Code Ann. § 8.01-216.3 and knowingly caused thousands of false claims to be made, used and presented to the Commonwealth of Virginia by their violation of federal and state laws, including the AKS, as described herein.

459. The Commonwealth of Virginia, by and through the Commonwealth of Virginia Medicaid program and other state health care programs, and unaware of Defendants' fraudulent and illegal practices, paid the claims submitted by health care providers and third payers in connection therewith.

460. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the Commonwealth of Virginia is connection with Defendants' fraudulent and illegal practices.

461. Had the Commonwealth of Virginia known that Defendants were violating the federal and state laws cited herein, it would not have paid the claims submitted by health care providers and third party payers in connection with Defendants' fraudulent and illegal practices.

462. As a result of Defendants' violations of Va. Code Ann. § 8.01-216.3 the Commonwealth of Virginia has been damaged in an amount far in excess of millions of dollars exclusive of interest.

463. Ms. Esther Sullivan is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Va. Code Ann. § 8.01-216.5(A) on behalf of herself and the Commonwealth of Virginia

464. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the Commonwealth of Virginia in the operation of its Medicaid program.

465. WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the COMMONWEALTH OF VIRGINIA:

Three times the amount of actual damages which the Commonwealth of Virginia has sustained as a result of Defendants' fraudulent and illegal practices;

A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendants caused to be presented to the Commonwealth of Virginia;

Prejudgment interest; and

All costs incurred in bringing this action.

To RELATOR:

The maximum amount allowed pursuant to Va. Code Ann. § 8.01-216.7 and /or any other applicable provision of law;

Reimbursement for reasonable expenses which Relator incurred in connection with this action;

An award of reasonable attorneys' fees and costs; and

Such further relief as this court deems equitable and just.

COUNT TWENTY-NINE

VIOLATION OF THE WISCONSIN CLAIMS FOR MEDICAL ASSISTANCE ACT

466. Relator re-alleges and incorporates the allegations in the preceding paragraphs as if fully set forth herein. Additionally, Relator states that the course of conduct described in this Complaint was a nationwide practice of Atrium Medical Corporation. Atrium Medical Corporation conducts business in the State of Wisconsin. Upon information and belief, Defendants' actions described herein occurred in the State of Wisconsin as well.

467. This is a qui tam action brought by Relator and the State of Wisconsin to recover treble damages and civil penalties under the Wisconsin False Claims for Medical Assistance Act, W.S.A. 20.931 *et seq.*

468. W.S.A. 20.931(2) provides liability for any person who-

> Knowingly presents or causes to be presented to any officer, employee, or agent of this state a false claim for medical assistance.
>
> Knowingly makes, uses, or causes to be made or used a false record or statement to obtain approval or payment of a false claim for medical assistance.
>
> Conspires to defraud this state by obtaining allowance or payment of a false claim for medical assistance, or by knowingly making or using, or causing to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Medical Assistance program.

469. In addition, W.S.A. 49.49(2) prohibits solicitation or receipt of any remuneration, including any kickback, bribe, or rebate, directly or indirectly, overtly or covertly, in cash or in kind, in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under any Wisconsin medical assistance program.

470. Defendants violated W.S.A. 49.49(2) by engaging in the fraudulent and illegal practices described herein.

471. Defendants furthermore violated W.S.A. 20.931(2) and knowingly caused thousands of false claims to be made, used and presented to the State of Wisconsin by their violation of federal and state laws, including W.S.A. 49.49(2) and the AKS, as described herein.

472. The State of Wisconsin, by and through the State of Wisconsin Medicaid program and other state health care programs, and unaware of Defendants' fraudulent and illegal

practices, paid the claims submitted by health care providers and third payers in connection therewith.

473. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Wisconsin in connection with Defendants' fraudulent and illegal practices.

474. Had the State of Wisconsin known that Defendants were violating the federal and state laws cited herein, it would not have paid the claims submitted by health care providers and third party payers in connection with Defendants' fraudulent and illegal practices.

475. As a result of Defendants' violations of W.S.A. 20.931(2) the State of Wisconsin has been damaged in an amount far in excess of millions of dollars exclusive of interest.

476. Ms. Esther Sullivan is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to W.S.A. 20.931(5) on behalf of herself and the State of Wisconsin.

477. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Wisconsin in the operation of its Medicaid program.

478. WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the STATE OF WISCONSIN:

> Three times the amount of actual damages which the State of Wisconsin has sustained as a result of Defendants' fraudulent and illegal practices;
>
> A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendants caused to be presented to the State of Wisconsin;

Prejudgment interest; and

All costs incurred in bringing this action.

To RELATOR:

The maximum amount allowed pursuant W.S.A. 20.931(11) and /or any other applicable provision of law;

Reimbursement for reasonable expenses which Relator incurred in connection with this action;

An award of reasonable attorneys' fees and costs; and

Such further relief as this court deems equitable and just.

DEMAND FOR JURY TRIAL

Relator hereby demands a jury trial.

Dated: May 26, 2015

Respectfully submitted,

UNITED STATES OF AMERICA
ex rel. Esther Sullivan

By: */s/ Caitlyn Silhan*

WATERS & KRAUS LLP
Daniel Hargrove, Esq.
600 Navarro St., Floor 5
San Antonio, Texas 78205
Tel. (210) 349-0515
Fax. (210) 349-3666
dhargrove@waterskraus.com

Loren Jacobson, Esq.
Charles S. Siegel, Esq.
3219 McKinney Ave.
Dallas, Texas 75204
Tel. (214) 357-6244
Fax. (214) 357-7252
ljacobson@waterskraus.com
siegel@waterskraus.com

STANDLY AND HAMILTON, LLP
Christopher S. Hamilton
Kevin Colquitt
325. N. St. Paul Street, Suite 3300
Dallas, Texas 75201
Tel. (214) 234-7900
Fax. (214) 234-7300
chamilton@standlyhamilton.com

LAW OFFICES OF JEFFREY A. NEWMAN
Jeffrey A. Newman, Esq. *(pro hac vice)*
One Story Terrace
Marblehead, MA 01945
Tel. (617) 823-3217
Fax. (781) 639-8688

jeffrey.newman1@gmail.com

TAIBI KORNBLUTH LAW GROUP, P.A.
Michael A. Kornbluth *(pro hac vice)*
North Carolina State Bar No. 27928
3100 Tower Blvd., Suite 800
Durham, NC 27707
Tel. (919) 401-4100
mak@tklawnc.com

ATTORNEYS FOR RELATOR

CERTIFICATE OF SERVICE

I hereby certify that on the 26th day of May 2015, a true and correct copy of the *Second Amended False Claims Act Complaint and Demand for Jury Trial* was served upon counsel of record via the Court's ECF system or by another manner authorized by Federal Rule of Civil Procedure 5(b)(2).

/s/ Caitlyn Silhan
Caitlyn Silhan